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| ADB258112 |
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Award Number: DAMD17-96-1-6262

TITLE: Early Stage Breast Cancer in Older Women: Predictors
Outcomes of Therapy

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CONTRACTING ORGANIZATION: Medical College of Wisconsin
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REPORT DATE: October 1999

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

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Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

| | | | | |
|--|---|--|---|-------------------------------|
| 1. AGENCY USE ONLY (Leave blank) | | 2. REPORT DATE October 1999 | 3. REPORT TYPE AND DATES COVERED Annual (15 Sep 98 - 14 Sep 99) | |
| 4. TITLE AND SUBTITLE Early Stage Breast Cancer in Older Women: Predictors Outcomes of Therapy | | | 5. FUNDING NUMBERS DAMD17-96-1-6262 | |
| 6. AUTHOR(S) Ann B. Nattinger, M.D., MPH | | | | |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Medical College of Wisconsin Milwaukee, Wisconsin 53226-0509 E-MAIL: anattng@mcw.edu | | | 8. PERFORMING ORGANIZATION REPORT NUMBER | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 | | | 10. SPONSORING / MONITORING AGENCY REPORT NUMBER | |
| 11. SUPPLEMENTARY NOTES | | | | |
| 12a. DISTRIBUTION / AVAILABILITY STATEMENT DISTRIBUTION STATEMENT: Distribution authorized to U.S. Government agencies only (proprietary information, Oct 99). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012. | | | | 12b. DISTRIBUTION CODE |
| 13. ABSTRACT (Maximum 200 Words) This study uses secondary data bases (SEER tumor registry records and Medicare claims data) to examine the relationship of primary breast cancer treatment to specific outcomes. Our studies of the accuracy and completeness of a Medicare claims algorithm for determining breast cancer surgery show that 94% of SEER patients undergoing breast cancer surgery are identified by a combination of Medicare claims. The physician part B claims identify a higher percentage of patients than do the inpatient claims alone. Using SEER and Medicare claims, we have determined that a substantial minority of women with early stage breast cancer undergo care that does not meet the 1990 NCI Consensus statement guidelines. Women who underwent breast-conserving surgery but neither axillary node dissection nor radiotherapy were at significantly higher risk of death, after adjusting for age, tumor size, and comorbid conditions. In preparation for studying the intermediate outcome of treatment for recurrent disease, a methodology has been developed for categorizing Medicare claims into those for initial treatment and those for recurrent disease treatment. The methodology utilizes a statistical model of number of claims and months after diagnosis to classify claims. | | | | |
| 14. SUBJECT TERMS Breast Cancer | | | 15. NUMBER OF PAGES 111 | |
| | | | 16. PRICE CODE | |
| 17. SECURITY CLASSIFICATION OF REPORT Unclassified | 18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified | 19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified | 20. LIMITATION OF ABSTRACT Limited | |

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

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| 1. <u>Du X, Freeman JL, Warren JL, Nattinger AB, Zhang D, Freeman DH, Goodwin JS.</u> Accuracy and Completeness of Medicare Claims Data for surgical Treatment of Breast Cancer. Med Care, 2000, in press. | |
| 2. <u>Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM.</u> Decrease in Appropriateness of Primary Therapy for Early Stage Breast Carcinoma Associated with Increased use of Breast-Conserving Surgery". 2000, submitted for publication. | |
| 3. <u>Du X, Freeman JL, Nattinger AB, Goodwin JS.</u> The effect of axillary node dissection on survival in women with early stage breast cancer. 2000, submitted for publication. | |
| 4. Ann B. Nattinger's C.V. | |

5.) INTRODUCTION

Almost half of the incident cases of breast cancer occur in women aged 65 and older. However, patients in this age group are infrequently enrolled into randomized clinical trials and have been seriously under-represented in the randomized trials of breast-conserving surgery (BCS) vs mastectomy. The randomized trials of younger women suggest that receipt of BCS without radiotherapy is associated with an increased risk of local disease recurrence, but no definite decrease in overall survival.

The goal of this study is to study outcomes associated with different breast cancer treatments in a population-based observational cohort of women aged 65 and older who have undergone surgical treatment for early stage breast cancer. The specific aims are:

1. To develop algorithms to utilize Medicare inpatient and outpatient data to define and study the treatments received and outcomes associated with the use of BCS with or without radiotherapy and mastectomy among older women with early stage breast cancer.
2. To determine predictors of receipt of radiotherapy among older women with early stage breast cancer who have undergone BCS.
3. To determine specific outcomes, especially treatment for local/regional disease recurrence, associated with receipt of BCS with radiotherapy, BCS without radiotherapy, and mastectomy among older women with early stage breast cancer.

To accomplish these aims we proposed methods for using the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registry data and Medicare claims files.

6.) BODY

Specific Aims #1: Algorithms Using Medicare Data.

In last year's report, provided data regarding the sensitivity and specificity of the Medicare claims with respect to diagnosis and treatment of breast cancer, using SEER data as the gold standard. Over this grant year we expanded the analysis from 1992 patients to a cohort of patients diagnosed in 1991-1993. Working with colleagues at the University of Texas and National Cancer Institute we also performed a logistic regression of the several characteristics as predictors of SEER-Medicare Concordance. These results are summarized in the attached manuscript, which has been accepted for publication in Medical Care (Du X, Freeman JL, Warren JL, Nattinger AB, Zhang D, Goodwin JS. Accuracy and completeness of Medicare claims data for surgical treatment of breast cancer. Med Care 2000, in press).

Although logistic regression techniques did not provide a better algorithm in terms of enhancing specificity, while maintaining sensitivity with the Medicare part B data (task 5), we still hope to apply the recursive partitioning technique to this problem. Dr. Craig Beam, our statistical expert in recursive partitioning, has returned to our institution after a year away, and we hope to work on this problem in the next year.

Specific Aims #2. Predictors of Radiotherapy.

As discussed in the previous report, this aim was expanded slightly to include axillary lymph node dissection and radiotherapy grouped as components of quality of care in patients undergoing breast-conserving surgery. The results have been written up as a manuscript for which revision has been invited by The Lancet. This manuscript is also attached (Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM. Decrease in appropriateness of primary therapy for early stage breast carcinoma associated with increased use of breast-conserving surgery.) This work has involved tasks 7-9.

Specific Aims #3. Outcomes of Primary Therapies for Early Stage Breast Cancer.

A. Survival among BCS patients not undergoing axillary lymph node dissection or radiotherapy.

As mentioned in last year's report, we have become aware that a substantial percentage of women undergoing BCS do not undergo axillary lymph node dissection, so have expanded specific aim #3 to include consideration of omission of axillary lymph node dissection, as well as omission of radiotherapy. We have studied (from the SEER data base), 26,290 early stage breast cancer patients aged 25 and older and who underwent BCS, and (from the SEER-Medicare linked data base) 14,089 early stage breast-cancer patients aged 65 and older who underwent BCS. In the SEER cohort, older women, unmarried women, and those with very small or very large tumors were less likely to undergo axillary lymph node dissection. Women who underwent axillary lymph node dissection had significantly greater survival, after adjusting for age, marital status, race, tumor size, and SEER site. Among the older women, receipt of radiotherapy and chemotherapy was determined using the SEER and Medicare claims. Of women undergoing BCS without axillary dissection, most did not receive radiation either.

Women who received neither axillary dissection nor radiotherapy were at significantly higher risk for death, compared to those receiving both axillary dissection and radiotherapy, after adjusting for age, tumor size, and comorbid conditions. Details are provided in the attached manuscript (Du X, Freeman JL, Nattinger AB, Goodwin JS. The effect of axillary node dissection on survival in women with early stage breast cancer. 2000, submitted or publication.) This work has involved tasks 6-8 and 11.

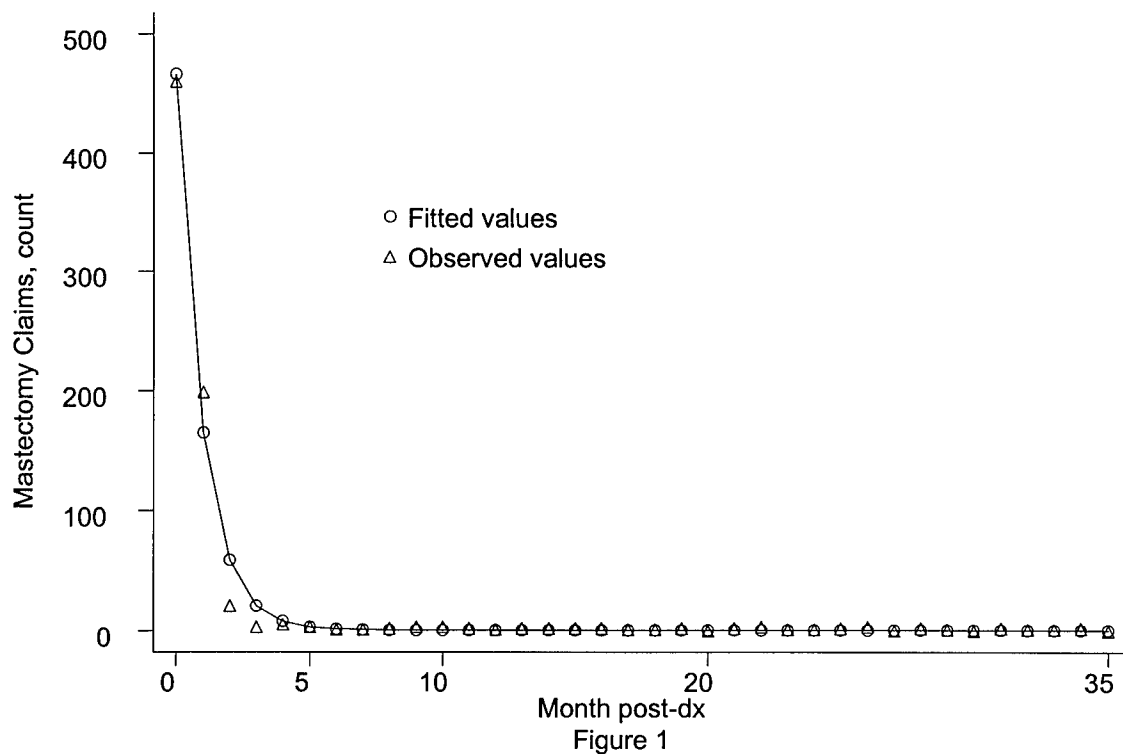
B. Intermediate Outcomes.

This specific aim also included determination of intermediate outcomes of mastectomy, radiotherapy, and chemotherapy after initial treatment, as a marker for recurrent disease. SEER does not include information on recurrent disease, so Medicare claims are being used to determine treatment for recurrent disease. This work involves tasks 10-11.

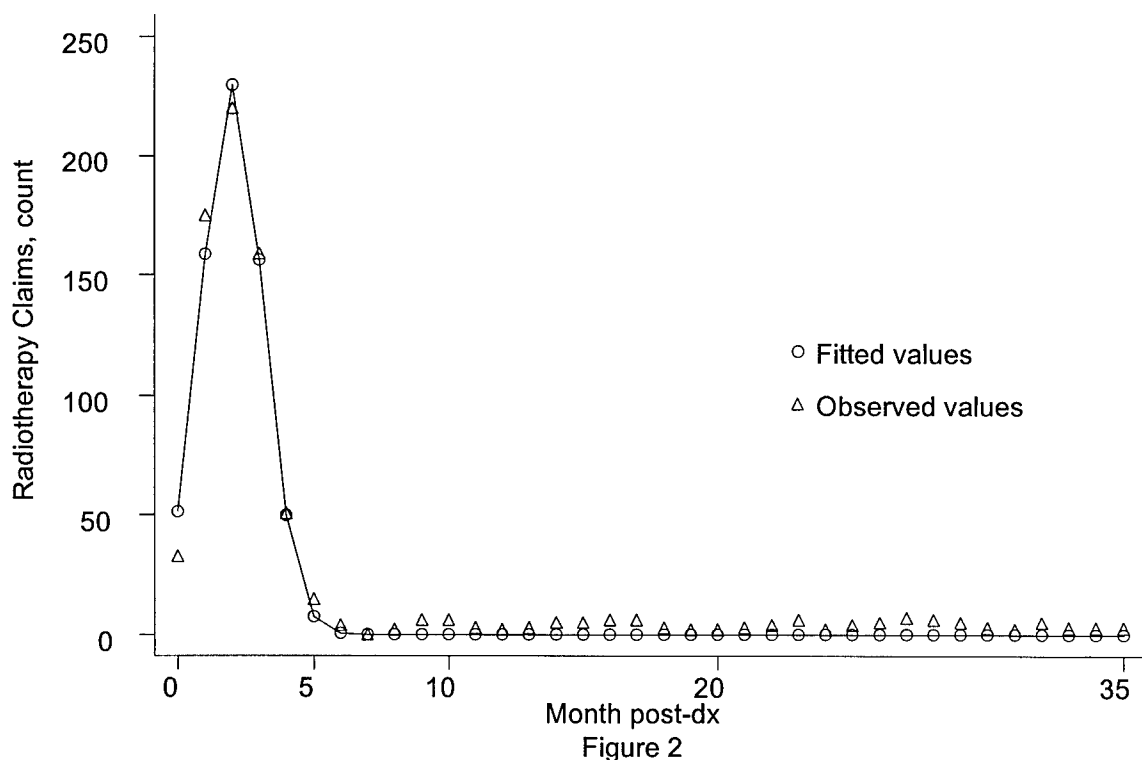
The initial analytic problem has been to determine which Medicare claims should be considered to represent initial treatment, and which represent treatment for recurrent disease. To address this issue, a population-based cohort of women in the SEER-Medicare linked data base has been selected. This cohort includes 2781 women aged 65 and older, who underwent mastectomy or BCS treatment in 1986 or 1987 for local or regional invasive breast cancer, and for whom Medicare part A and B claims were available for at least 6 years following diagnosis or until death. Date of diagnosis, initial treatment type (BCS or mastectomy), stage (local or regional), and initial use or radiotherapy have been determined according to the SEER data.

For patients in this cohort, all mastectomy, radiotherapy and chemotherapy claims have been determined using Medicare part A and B claims, and the number of months after diagnosis was determined for each claim. For each therapy (mastectomy, radiotherapy, and chemotherapy) the distribution of claims has been separately modelled. In each model, there is a high number of claims in the first months after diagnosis, followed by an almost uniform distribution of claims. For example, among patients initially treated with mastectomy according to SEER, the occurrence of mastectomy claims in Medicare is best modeled as an exponential function (see Fig. 1). By six months after the SEER date of diagnosis, this function falls to a uniform distribution. Therefore, a cutoff of six months after diagnosis is taken to be the point after which mastectomy claims can be presumed to represent treatment for recurrent disease.

Similarly, radiotherapy is best modeled as a lognormal distribution (Fig. 2), which falls to a uniform distribution by 8 months after the date of diagnosis. Chemotherapy could be modelled only using regional stage patients, as the occurrence of chemotherapy claims among local stage patients was so low. For chemotherapy (Fig. 3) a number of potential distributions were considered, including normal, lognormal, gomertz, and exponential distributions. The normal distribution was selected as providing the best fit, and this distribution fell to a uniform distribution by 15 months after diagnosis. These cutoffs for claims representing initial vs recurrent disease treatment will be used in determining the occurrence of intermediate outcomes in further analyses relating to specific aim #3.

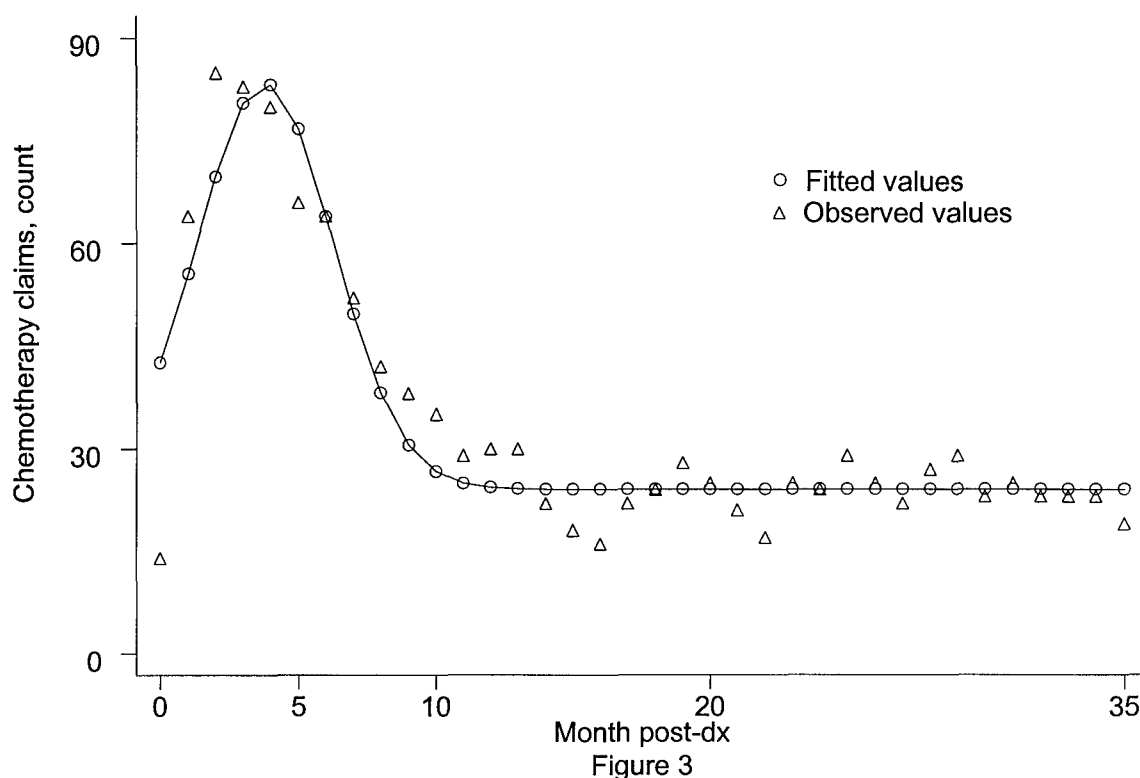


Occurrence of Medicare claims for mastectomy among older women with local stage breast cancer, who were treated with initial mastectomy according to the SEER data. The triangles represent observed values, and the circles represent fitted values, based on an exponential function.



(Proprietary data)

Occurrence of Medicare claims for radiotherapy among older women with local stage breast cancer, who were treated with initial radiotherapy according to the SEER data. The triangles represent observed values and the circles represent fitted values, based on a lognormal distribution.



Occurrence of Medicare claims for chemotherapy among older women with regional stage breast cancer. The triangles represent observed values and the circles represent fitted values, based on a normal distribution.

7.) KEY RESEARCH ACCOMPLISHMENTS

- Determination of agreement of SEER and Medicare data bases for surgical treatment of breast cancer.
- Determination of relative completeness of different types of Medicare claims for breast cancer operations recorded by SEER.
- Development of predictors of concordance between SEER and Medicare data bases.
- Determination of percentage receipt of appropriate care (BCS patients who have undergone radiation and axillary lymph node dissection and total mastectomy patients who have undergone axillary lymph node dissection) over time.
- Determination of predictors of appropriate care, in terms of age, urban vs rural residence, and type of surgery.

- Determination of predictors of axillary node dissection, relationship of receipt of axillary dissection to receipt of radiotherapy and relationships to survival, among BCS patients.
- Development of methodology for partitioning mastectomy, radiotherapy, and chemotherapy claims into initial therapy or therapy for recurrent disease.

8.) REPORTABLE OUTCOMES

- Du X, Freeman JL, Warren JL, Nattinger AB, Zhang D, Freeman DH, Goodwin JS. Accuracy and Completeness of Medicare Claims Data for surgical Treatment of Breast Cancer. Med Care, 2000, in press.
- Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM. Decrease in Appropriateness of Primary Therapy for Early Stage Breast Carcinoma Associated with Increased use of Breast-Conserving Surgery". 2000, submitted for publication.
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- Beam CA, Guse C, Nattinger AB. Do outpatient records improve the accuracy of Medicare breast cancer claims data? J Gen Intern Med 1998;13 (suppl):41. Presented at the Society of General Internal Medicine National Meeting, April 23-25, 1998, Chicago, IL.
- Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM. Decrease in appropriateness of breast cancer care associated with increased use of breast-conserving surgery. J Gen Intern Med 1999;14 (suppl 2):58. Presented at the 22nd Annual National SGIM meeting in San Francisco, CA, April 29-May 1, 1999.
- "Outcomes of Older Women with Early Stage Breast Cancer", R0-1 submission to NIH-NCI 10/99, P.I.: Ann B. Nattinger, MD, based in part on work supported by this award.

9.) CONCLUSIONS

Medicare claims identify about 95% of tumor registry patients undergoing mastectomy, and 88% of such patients undergoing BCS for breast cancer treatment. Physician claims identify the most cases, followed by inpatient claims and then outpatient claims. Factors

associated with increased concordance of Medicare and SEER data bases are older age, white race, and local or regional stage disease.

Between 1983 and 1995, the percentage of a population-based cohort undergoing care termed appropriate by the 1990 NIH Consensus Statement on early stage breast cancer fell from 88% to 78%. The decrease in appropriateness occurred in all age groups, and was more marked among women residing in more urban areas. The decrease in appropriateness of care is attributable mostly to women receiving BCS without radiotherapy and/or without axillary lymph node dissection. Older women who undergo BCS without axillary dissection and without radiotherapy have poorer survival than expected, after adjusting for demographics, tumor size, and comorbid diseases.

10.) REFERENCES

1. Du X, Freeman JL, Warren JL, Nattinger AB, Zhang D, Freeman DH, Goodwin JS. Accuracy and Completeness of Medicare Claims Data for surgical Treatment of Breast Cancer. Med Care, 2000, in press.
2. Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM. Decrease in Appropriateness of Primary Therapy for Early Stage Breast Carcinoma Associated with Increased use of Breast-Conserving Surgery". 2000, submitted for publication.
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11.) APPENDICES

1. Du X, Freeman JL, Warren JL, Nattinger AB, Zhang D, Freeman DH, Goodwin JS. Accuracy and Completeness of Medicare Claims Data for surgical Treatment of Breast Cancer. Med Care, 2000, in press.
2. Nattinger AB, Hoffmann RG, Kneusel RT, Schapira MM. Decrease in Appropriateness of Primary Therapy for Early Stage Breast Carcinoma Associated with Increased use of Breast-Conserving Surgery". 2000, submitted for publication.
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4. Ann B. Nattinger's C.V.

Main title:

Accuracy and completeness of Medicare claims data for surgical treatment of breast cancer

Brief title: **Medicare surgery for breast cancer**

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Key words: breast cancer, mastectomy, breast conserving surgery, SEER, Medicare.

Word count: 3,220 words of text, excluding abstract (250 words), acknowledgements, references & 4 tables.

Accuracy and completeness of Medicare claims data for surgical treatment of breast cancer

Abstract (word count: 250 words)

BACKGROUND. Although a number of studies have used Medicare claims data to study trends and variations in breast cancer treatment, the accuracy and completeness of information on surgical treatment for breast cancer in the Medicare data have not been validated.

OBJECTIVES. This study assessed the accuracy and completeness of Medicare claims data for breast cancer surgery in order to determine whether Medicare claims can serve as a source of data to augment information collected by cancer registries.

METHODS. We used the Surveillance, Epidemiology and End Results (SEER) Cancer Registry-Medicare data and compared Medicare claims on surgery with the surgery recorded by the SEER registries for 23,709 women diagnosed with breast cancer at ≥ 65 from 1991 through 1993.

RESULTS. Over 95% of women having mastectomy according to the Medicare data were confirmed by SEER. For breast conserving surgery, 91% of cases were confirmed by SEER. The Medicare physician services claims and inpatient claims were approximately equal in accuracy on type of surgery. The Medicare outpatient claims were less accurate for breast conserving surgery. In terms of completeness, when the three claims sources were combined, 94% of patients receiving breast cancer surgery according to SEER were identified by Medicare.

CONCLUSIONS. The combined Medicare claims database, which includes the inpatient, outpatient and physician service claims, provides valid information on surgical treatment among women known to have breast cancer. The claims are a rich source of data to augment the information collected by tumor registries and also provide information that can be used to follow long-term outcomes of Medicare beneficiaries.

treatment²⁰ have raised questions about the completeness and accuracy of claims for surgery performed outside the hospital.

This study was conducted to assess the accuracy and completeness of Medicare data for surgery, using all available Medicare claims sources: hospital inpatient, hospital outpatient and physician services data. Of interest is the extent to which the claims provide information on breast cancer related surgery in the first course of therapy and whether the type of surgery is confirmed by an external source of data. The overall goal is to determine, using a cohort of women reported by cancer registries as having breast cancer, whether Medicare claims can serve as a source of data to augment information collected by cancer registries and be used describe surgical treatment patterns in older women with breast cancer.

Methods

Data sources

We used the merged Surveillance, Epidemiology and End Results (SEER)-Medicare database for this analysis. The SEER program, supported by the National Cancer Institute, includes population-based tumor registries in selected geographic areas. In 1992, these areas included the metropolitan areas of San Francisco/Oakland, Detroit, Atlanta and Seattle; Los Angeles county; the San Jose-Monterey area; and the states of Connecticut, Iowa, New Mexico, Utah and Hawaii.²¹ These areas cover approximately 14% of the U.S. population.²¹ The registries ascertain all newly diagnosed (incident) breast cancer cases from multiple reporting sources such as hospitals, outpatient clinics, laboratories, private medical practitioners, nursing/convalescent homes/hospices, autopsy reports and death certificates.^{13,22,23} Information includes tumor location, size and histologic type; demographic characteristics such as age, gender, race and marital status; and types of treatment provided within four months after the date of diagnosis.²² In the case of surgery, SEER records the most invasive surgery.

The Medicare Program is administered by the Health Care Financing Administration (HCFA). It covers hospital, physician and other medical services for more than 97% of persons aged 65 years or older.^{13,23} The Medicare claims data used in the study included the following three files: (1) Medicare Provider Analysis and Review file, which contains inpatient hospital claims; (2) the Hospital Outpatient Standard Analytic File, which contains the claims for outpatient facility services; and (3) the 100% Physician/Supplier file, which contains the claims for physicians' and other medical services. These data were available for all beneficiaries starting

in 1991. Therefore, we used all cases diagnosed between January 1, 1991 and December 31, 1993.

Cases reported by the SEER registries from 1973 to 1993 have been matched against the Medicare's master enrollment file. Of persons aged 65 and over appearing in the SEER records, Medicare eligibility could be identified for 94% of these cases. The method of linking these data has been described elsewhere.^{13,20} For SEER cases found to be Medicare eligible, their claims are available through 1994.

Study population

The study population consisted of all female patients diagnosed with breast cancer at age 65 and older between 1991 and 1993. Excluded were women who did not have full coverage of both Medicare Part A and Part B, or who were members of Health Maintenance Organizations in the year of diagnosis because claims from these organizations may not be included in the HCFA databases. Also excluded were 61 patients whose month of diagnosis was unknown, and 126 patients with no information from SEER on surgical treatment. This left 23,709 patients for analysis (8,022 in 1991; 8,056 in 1992; and 7,631 in 1993).

Variable definitions

Breast cancer-directed surgery

In SEER, breast conserving surgery (BCS) was defined as segmental mastectomy, lumpectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, excisional biopsy, or partial mastectomy unspecified, with or without dissection of axillary lymph nodes.

Mastectomy was defined as subcutaneous, total (simple), modified radical, radical or extended radical mastectomy.

In Medicare, BCS was defined with the following codes: ICD-9-CM²⁴ procedure codes 8521 (local excision), 8522 (quadrantectomy), 8523 (subtotal mastectomy), or common procedure terminology (CPT)²⁵ codes 19120 (local excision), 19160 partial mastectomy) or 19162 (partial mastectomy with axillary dissection). Mastectomy was defined with the following codes: ICD-9-CM procedure codes 8541-8542 (simple mastectomy), 8543-8544 (modified radical), 8545-8548 (radical) or a CPT code on a physician or outpatient claim of 19240 (modified radical) or 19220 (radical), or 19180 (simple mastectomy).

Analyses

Medicare claims for surgical treatment were categorized into three groups: mastectomy, BCS and no cancer-directed surgery. Women were considered to have received mastectomy if any of three Medicare claim sources (inpatient or outpatient or physician/supplier claims) indicated so, regardless of whether or not they had any claims for BCS. If they had claims for BCS only, they were defined as having received BCS. If they had neither claims for mastectomy nor for BCS, they were considered to have no cancer-directed surgery.

Since SEER collects only information on treatment within four months following the date of diagnosis,²³ we examined all Medicare claims from 1991 to 1994 for surgery that were made within four months (122 days) of the date of diagnosis. As SEER reported only the month and year of diagnosis, we therefore arbitrarily defined the day of diagnosis in SEER as the 15th of the

month. Date of surgery was determined from the claims source that first identified the type of surgery (mastectomy or BCS). For inpatient claims, it was defined as the date of admission. For outpatient and physician claims, it was defined as the earliest date of service.

Patient and tumor characteristics such as age, race, tumor stage, and geographic areas are available from the SEER data. The simple kappa statistic was calculated to quantify the degree of agreement in surgical treatment categories between the two databases.²⁶ The odds ratios of concordance on surgical treatment between the two data bases were generated from multivariate logistic regression analyses. These analyses adjusted for age, race, tumor stage and geographical area, because previous studies have found that the degree of agreement of information on treatment is affected by these factors^{8,9,11,12,20}. Four metropolitan areas (San Francisco/Oakland was combined with Los Angeles county and the San Jose-Monterey area in California) and five states, forming nine areas, were adjusted in the analysis. All computer programming and analyses were completed using the SAS system.²⁷

Results

Table 1 presents comparisons of surgical treatment between the SEER and Medicare databases in women with breast cancer diagnosed from 1991 through 1993. Of 13,431 women having mastectomy according to the Medicare data, 95% were confirmed by SEER. For BCS, 88% of cases were confirmed by SEER. The simple kappa statistic for overall agreement on surgery between SEER and Medicare was 0.75 (95% confidence interval: 0.74-0.76). From Table

44% of those receiving BCS according to SEER, but only for 27% of those receiving mastectomy (Table 3). The inpatient claims had data on 86% of those receiving mastectomy and only 34% of those receiving BCS. The physician claims showed similar degrees of completeness of information on surgery for patients receiving mastectomy (91%) and BCS (91%). Of 13,341 patients with mastectomies and 8,213 with BCSs, 54 (0.4%) of patients with mastectomy and 166 (2.0%) patients with BCS were identified by the outpatient claims, and were not identified in either the inpatient or physician claims. When the three claims sources were combined, 94% of surgery according to SEER were identified by Medicare.

Table 4 presents three different comparisons of information on receipt of surgery between the two databases. The percentage of patients in whom there is agreement on receipt of surgery is given, as is the kappa statistic, as a function of patient and tumor characteristics. The last column was a multivariate analysis, showing the odds of a patient having concordant information regarding receipt of surgery between the two databases. Concordance between the two data sets was significantly greater in older women and in whites. Agreement on receipt of surgery was significantly better in those with local or regional stage but much lower in those with distant or unstaged as compared to those with in-situ cancer. There was variation among the nine SEER areas in the extent of concordance on type of surgery between SEER and Medicare, ranging from 81% to 90% (*data not shown*). When the region variables were excluded from the model, the magnitude of the odds ratios for other variables changed slightly, but the direction and significance of the odds ratios remain unchanged.

Discussion

The question addressed by this study is whether the Medicare claims data provide valid information on surgical treatment for patients known to have breast cancer. This question has two components: one involves accuracy and the other is completeness. We examined these issues for each of the three sources of Medicare claims and for the combined data from all three sources. When we were addressing these issues, we used the SEER data as the reference group. This is because the SEER program was primarily designed to provide information on cancer incidence, mortality and treatment outcomes,²¹ while the Medicare claims data are administrative in nature and not designed for research purposes.^{1-6,11-13}

In terms of accuracy, among patients for whom information on type of surgery was available from both Medicare and SEER, 95% of patients who received mastectomy according to the combined Medicare claims were confirmed by SEER. Of those who received BCS, 91% were confirmed by SEER. The Medicare physician services claims and inpatient claims were approximately equal in accuracy on type of surgery. The Medicare outpatient claims were less accurate for BCS. The concordance is greater in older women (≥ 75 years) and in patients with local or regional stage cancer, but varies among the SEER areas.

The accuracy of Medicare data on breast cancer surgery has also been studied using different reference groups such as re-abstracted records or local cancer registry data. Fisher et al¹² compared Medicare inpatient hospitalization codes for mastectomy with that identified from the

re-abstracted hospital record. Of those mastectomies identified by the re-abstracted record, 97% were found to have a code for mastectomy in Medicare data. However, only 33 cases were reviewed. In another study, discharge data from one hospital in New York City were compared with hospital cancer registry data. The study found a high concordance rate for mastectomy between the two databases.¹⁸ Warren et al²⁰ described a comparison of mastectomy between Medicare and SEER in patients who only underwent mastectomy in 1992-93. The agreement rate was 95% for inpatients and 89% for outpatients.²⁰ These previous studies on breast cancer surgery depended on the Medicare inpatient or outpatient claims data but did not use the physician claims data. We found in this study that information on surgery identified from the physician service claims was similar in accuracy as compared to the inpatient claims. Only 50% of BCS from the outpatient claims could be identified by SEER. This may largely reflect clinical practice patterns, because many women who had BCS in the outpatient settings for diagnostic purposes may end up with a mastectomy in hospitals. Therefore, the combined data from all three sources of Medicare claims should generate the most accurate information on surgery

We also found that any single Medicare claims source did not provide complete information on surgery (Table 3), although Medicare physician claims seemed the most complete among the three Medicare claims sources. Medicare outpatient claims, though least complete, still identified 0.4% of patients with mastectomy and 2.0% of cases with BCS, which otherwise were not identified by either inpatient or physician claims. When the three claims sources were combined, 94% of patients receiving breast cancer surgery according to SEER were identified by Medicare.

A number of factors might have contributed to reduce the completeness of the Medicare data on surgery. First, information on surgery from Medicare was restricted to those who had claims within 4 months after date of diagnosis. This made it compatible with SEER data because SEER only collects information within this period.²³ However, this might have excluded those who had late claims for surgery and thus underestimate the degree of agreement between two data sets. We did additional analyses extending the time frame from 4 to 12 months after diagnosis. As a result, the overall agreement between SEER and Medicare on type of surgery improved ($\kappa=0.78$ as compared to 0.75 in Table 1).

Second, younger patients who recently became eligible for Medicare coverage might have less complete information in Medicare claims records. Indeed younger age was a risk factor for lack of concordance between Medicare and SEER (Table 4). Third, if patients switched their care to Health Maintenance Organizations or received care in Veterans Affairs hospitals, they may have missing information in the Medicare claims. Finally, it may be possible that a very small proportion of patients in SEER were mismatched with the Medicare data. If this happened, those patients would not have had Medicare claims for breast cancer surgery.

As previous studies also showed, Medicare claims data on the validity of mastectomy¹² have been found to have a high level of accuracy. In this study we demonstrated that information on mastectomy as well as BCS is reasonably accurate and complete for women known to have breast cancer. Hence, using a linked database of tumor registry data with Medicare claims can overcome the limitations in using claims data alone that were noted in previous validation studies of cancer stage¹⁶ and incident case ascertainment with Medicare data¹⁵.

It should be kept in mind that there were some limitations in this study. First, this analysis used only the Medicare claims for women identified from the SEER data as having cancer. The accuracy and completeness of breast cancer related procedures for non-SEER cases is unknown. It is important to note that the presence of Medicare claim with a breast cancer related procedure does not confirm that the woman had cancer, as some procedures, such as BCS, may be used for diagnostic as well as therapeutic purposes. Second, the SEER data were assumed to be correct as the reference group. We found a portion of women with breast cancer who received cancer-directed surgery according to the Medicare claims data that were not recorded in the SEER data. For example, of 1,019 patients who did not have surgery according to SEER, 345 (34%) had claims for such a surgery in Medicare (Table 1). As previous investigators^{11,23,28} also demonstrated, SEER might not provide complete information on treatment because it might sometime miss information from outpatient settings and might not record those who moved immediately after diagnosis or underwent treatment in an out-of-state facility.²⁹ Furthermore, this study was performed in a cohort of women who were diagnosed with breast cancer and were successfully linked with Medicare data (94% match rate¹³). Also excluded were cases enrolled with health maintenance organizations and those without coverage of both Medicare Part A and Part B in 1991-93. It is unknown whether the two data bases would agree on type of surgery for those cases excluded, particularly those that were not ascertained by SEER as breast cancer but identified by Medicare data alone. Nevertheless, there was no external validation of the information on receipt of surgical treatment to assess the accuracy of the Medicare and SEER data sources and to determine which data source is "correct". This may be achieved by reviewing the medical records for a sample of patients with breast cancer. However,

all patient identifiers were removed from the final SEER-Medicare linked database for confidentiality reasons, precluding these analyses.

In conclusion, the combined Medicare claims database, which includes the inpatient, outpatient and physician service claims, provides valid information on surgical treatment among women known to have breast cancer. The claims are a rich source of data to augment the information routinely collected by tumor registries. In particular, it provides information on receipt of medical services that can be used to examine patterns of care and follow long term outcomes of Medicare beneficiaries.

Acknowledgments

This study was supported by grants from the Department of Defense (DAMD17-97-1-709-5, DAMD17-96-6262, and DAMD17-99-1-9397), the National Cancer Institute (CA72076) and the Sealy & Smith Foundation. This study used the Linked SEER-Medicare Database. The interpretation and reporting of these data are the sole responsibilities of the authors. The authors acknowledge the efforts of the Applied Research Branch, Division of Cancer Prevention and Population Science, NCI; the Office of Information Services, and the Office of Strategic Planning, HCFA; Information Management Services (IMS), Inc.; and the SEER Program tumor registries in the creation of the SEER-Medicare Database.

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Table 1. Comparison of surgical treatment between SEER and Medicare claims made within 4 months after the date of diagnosis for women with breast cancer diagnosed from 1991 to 1993

| | | Medicare * | | | |
|------|--|----------------------------|---------------------------|---------------------------|----------------|
| | Surgery categories (row %) (column %) | No cancer-directed surgery | Breast conserving surgery | Mastectomy | Total |
| | No cancer-directed surgery | 674 (66.1) (32.6) | 258 (25.3) (3.1) | 87 (8.5) (0.7) | 1,019 (100.0) |
| SEER | Breast conserving surgery | 477 (5.7) (23.1) | 7231 (86.4) (88.0) | 658 (7.9) (4.9) | 8,366 (100.0) |
| | Mastectomy | 914 (6.4) (44.3) | 724 (5.1) (8.8) | 12,686 (88.6) (94.5) | 14,324 (100.0) |
| | Total | 2,065 (100.0) | 8,213 (100.0) | 13,431 (100.0) | 23,709 |

* Claims for surgical treatment were identified from the hospital inpatient or hospital outpatient or physician services files in Medicare database and only those claims for surgery made within 4 months after the date of diagnosis of breast cancer were counted here. Women were considered to have received mastectomy if any of three Medicare claim sources (inpatient or outpatient or physician claims) indicated so, regardless of whether or not they had any claims for BCS. If they had claims for BCS only, they were defined as having received BCS. If they had neither claims for mastectomy nor for BCS, they were considered to have no cancer-directed surgery.

Table 2. Accuracy of information on the type of surgery in the Medicare claims database as compared to SEER

| Sources of the Medicare claims | Percent of cases with claims for mastectomy in Medicare files confirmed identified by SEER % (number identified by SEER/number in Medicare) * | Percent of cases with claims for BCS in Medicare files confirmed by SEER % (number identified by SEER/number in Medicare) * |
|--|--|--|
| Medicare physician claims | 96.2 (12,096/12,580) | 87.9 (7,105/8,087) |
| Medicare inpatient claims | 96.0 (12,087/12,586) | 91.3 (2,369/2,596) |
| Medicare outpatient claims | 82.8 (231/279) | 49.7 (3,612/7,269) |
| Three Medicare claims combined ** | 95.1 (12,686/13,344) | 90.9 (7,231/7,955) |

* The analyses are restricted to those cases where a surgical therapy is coded in both SEER and the particular Medicare data base being assessed for accuracy. As a result, denominators varied by paired comparisons (including the combined numbers at the bottom of the table).

** If there was a claim for mastectomy in any of the three Medicare claims sources (hospital inpatient or hospital outpatient or physician claims files), the case was categorized as mastectomy. Otherwise, the case was categorized as breast conserving surgery (BCS). Only claims for surgery made within 4 months after the date of diagnosis of breast cancer were examined to ascertain BCS.

Table 3. Completeness of the Medicare claims on surgery (mastectomy or breast conserving surgery) for women with breast cancer diagnosed from 1991 through 1993

| Sources of the Medicare claims | Number (%) of patients with <i>mastectomy</i> according to SEER that were identified by Medicare claims as having any surgery * (n=14,324) | Number (%) of patients with <i>breast conserving surgery</i> according to SEER that were identified by Medicare claims as having any surgery * (n=8,366) | Number (%) of patients with either <i>mastectomy</i> or <i>breast conserving surgery</i> according to SEER that were identified by Medicare claims as having any surgery (n=22,690) |
|--------------------------------|---|---|--|
| Physician claims | 13,078 (91.3) | 7,589 (90.7) | 20,667 (91.1) |
| Inpatient claims | 12,314 (86.0) | 2,868 (34.3) | 15,182 (67.9) |
| Outpatient claims | 3,888 (27.1) | 3,660 (43.7) | 7,548 (33.2) |
| 3 claims combined † | 13,410 (93.6) | 7,889 (94.3) | 21,299 (93.9) |

* Surgery includes either mastectomy or breast conserving surgery.

† Medicare claims for surgery were identified from the hospital inpatient or hospital outpatient or physician services files. Only claims for surgery made within 4 months after the date of diagnosis of breast cancer were examined to ascertain breast cancer surgery. If there was a claim for mastectomy in any of the claims sources, the case was categorized as mastectomy. Otherwise, the case was categorized as breast conserving surgery.

Table 4. Comparison of surgical treatment between SEER and Medicare in women with breast cancer diagnosed from 1991 through 1993

| Characteristics From SEER registry | Medicare | | Number (%) of concordant cases | SEER Adjusted odds ratio of being concordant (95% confidence interval) † |
|---------------------------------------|-----------------------|--|-----------------------------------|---|
| | Number of patients | Simple Kappa (95% confidence interval) | | |
| All patients | 23,709 | 0.75 (0.74-0.76) | 86.8 | - |
| <i>Age</i> | | | | |
| 65-74 | 12902 | 0.71 (0.70-0.72) | 84.8 | 1 |
| 75-84 | 8408 | 0.79 (0.78-0.80) | 88.9 | 1.39 (1.27-1.52) |
| 85+ | 2399 | 0.84 (0.82-0.86) | 90.5 | 1.51 (1.30-1.76) |
| <i>Race</i> | | | | |
| White | 21534 | 0.75 (0.74-0.76) | 87.0 | 1 |
| Black | 1342 | 0.73 (0.70-0.76) | 84.1 | 0.79 (0.67-0.94) |
| Other | 833 | 0.77 (0.73-0.81) | 87.2 | 1.17 (0.90-1.53) |
| <i>Cancer stage</i> | | | | |
| In situ | 2176 | 0.74 (0.71-0.76) | 86.0 | 1 |
| Local | 13546 | 0.77 (0.76-0.78) | 88.3 | 1.26 (1.09-1.45) |
| Regional | 5051 | 0.70 (0.68-0.73) | 88.8 | 1.44 (1.23-1.69) |
| Distant | 914 | 0.58 (0.53-0.62) | 71.8 | 0.39 (0.32-0.48) |
| Unstaged | 2022 | 0.68 (0.65-0.70) | 79.6 | 0.56 (0.47-0.68) |

† Odds ratios were derived from the logistic regression model, adjusted for the variables listed in the table and nine SEER areas. Lemeshow goodness of fit statistic = 7.1848 with 8 degrees of freedom (P=0.5168).

Decrease in Appropriateness of Primary Therapy for Early Stage Breast Carcinoma
Associated with Increased Use of Breast-Conserving Surgery

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Grant support from Department of Defense, Grant No. DAMD17-96-1-6262.

Presented in abstract form at the national meeting of the Society of General Internal
Medicine, San Francisco, CA, April 28-30, 1999.

Running Head: Appropriateness of Breast Cancer Care

ABSTRACT

Background

Breast-conserving surgery (BCS) is a more complex treatment for breast cancer than is mastectomy, due to the need for a separate incision for axillary lymph node dissection, and for postoperative radiotherapy. We hypothesized that the adoption of this therapy into clinical practice might be characterized by gaps between the care recommended and the care actually delivered.

Methods

We used the United States national Surveillance, Epidemiology, and End Results tumor registry records to study 144,759 women aged 30 and older who were treated for early stage breast cancer between 1983 and 1995. We determined the percentage undergoing at least the minimum appropriate primary treatment (defined as total mastectomy with axillary node dissection or BCS with axillary node dissection and radiotherapy) during each calendar quarter.

Results

The percentage of women receiving appropriate primary therapy fell from 88% in 1983-1989 to 78% by the end of 1995. The decrease in appropriateness of care occurred in all age groups, and in women with both local and regional stage disease. By the end of 1995, 76% of women residing in more urban areas underwent appropriate care, compared to 85% of those residing in more rural areas. The decrease in appropriateness was

attributable mostly to women receiving BCS without radiotherapy or without axillary node dissection.

Conclusions

The appropriateness of care for early stage breast cancer in the U.S. has declined from 1990-95. Ironically, this decline is due to greater use of BCS, coupled with omission of radiotherapy and/or axillary node dissection among a substantial percentage of women undergoing this treatment.

Key Words: Breast Cancer, Mastectomy, Breast-Conserving Surgery, Appropriateness of Care, Tumor Registry Data.

INTRODUCTION

In June of 1990, an NIH Consensus Development Conference on the treatment of early stage breast cancer held that either breast conservation treatment or total mastectomy were appropriate for the majority of women with stage I or II breast cancer. This consensus statement also clarified that either operation should include an axillary lymph node dissection, and that breast-conserving surgery (BCS) should be accompanied by radiotherapy. ⁽¹⁾ Breast conservation was considered preferable to mastectomy treatment ⁽¹⁾ but is arguably more complex than mastectomy. Breast conservation requires a separate incision for axillary lymph node dissection, postoperative radiotherapy, attention to the tumor margins, and attention to the cosmetic result. ⁽²⁾

The use of BCS increased during the early 1980's, ⁽³⁾ remained generally stable during the late 1980's ^(4,5) and increased further from about 1990 on. ⁽⁶⁻¹⁰⁾ One might expect that the adoption of a more complex therapy into clinical practice would be characterized by some gaps between the care recommended and the care actually delivered. In fact, it has been reported previously that women undergoing BCS do not universally undergo radiotherapy. ^(3, 10, 11)

In this study, we determined the use of appropriate primary therapy, as articulated by the 1990 NIH consensus conference, over the time period 1983-1995. We provide evidence that the use of therapy deemed appropriate by the consensus statement actually decreased over the years immediately following its publication, concurrent with a substantial increase in the use of conservative surgery.

METHODS

The National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) registry⁽¹²⁾ was the source of data on breast cancer patients and their care. The SEER data were collected by nine geographically distinct population-based tumor registries, and included information on demographic characteristics, extent of disease, and initial treatment for approximately 10% of U.S. cancer patients. The nine SEER sites included comprised the entire states of Connecticut, Hawaii, Iowa, New Mexico, and Utah, and the metropolitan areas of Atlanta, Detroit, Seattle-Puget Sound, and San Francisco-Oakland.

To further characterize the study population, we obtained from the federal Area Resource File⁽¹³⁾ information regarding the urban vs rural status of the county of residence of the patient.

Patients

We initially selected 147,432 women who were aged 30 or older at the time of first diagnosis of an invasive local or regional stage unilateral breast cancer between 1983 and 1995. We have utilized similar methods previously.^(6, 7) We excluded 1887 (1.3%) women who did not undergo primary therapy with BCS or mastectomy, or whose type of surgery was unknown. We excluded 55 women (0.04%) whose date of diagnosis was unknown. These exclusions left a cohort of 145,490 women.

Definitions of Analytic Variables

Based on SEER convention, the cancer was considered localized if it was confined to the breast tissue, and regional if it had extended into surrounding tissue or regional lymph nodes. The more precise AJCC staging was not recorded until 1988, so could not be used for the primary analyses. The AJCC staging and tumor size information was used for a subgroup analysis of women treated in 1988 or later.

Patients were categorized by SEER as having received BCS if they underwent segmental mastectomy, lumpectomy, quadrantectomy, tylectomy, wedge resection, excisional biopsy, or partial mastectomy. All other women underwent some form of mastectomy. Patients were categorized as undergoing radiotherapy if they underwent any form of radiotherapy according to SEER. Patients were categorized as not undergoing radiotherapy if SEER recorded them as undergoing no radiotherapy or refusing radiotherapy.

The patients were grouped by age at diagnosis (30-49 years, 50-64 years, 65-79 years, or 80 and older). Their race was categorized as white, black, or other. The size of the metropolitan statistical area (MSA) of the county of residence of the patient was categorized as $\leq 250,000$ persons or $> 250,000$ persons. For 85 (0.06%) of the patients, a valid code for county of residence was not available. Such patients were excluded from analyses of urban vs rural status, but were included in other analyses.

Based upon the June, 1990 U.S. NIH Consensus Development Conference⁽¹⁾, the minimum requirements for appropriate primary therapy were determined to be total mastectomy with axillary lymph node dissection or BCS with axillary lymph node dissection and radiotherapy. Women who underwent subcutaneous mastectomy, total mastectomy without lymph node dissection, BCS without radiotherapy, or BCS without

lymph node dissection were categorized as not meeting the consensus standard. For 731 (0.5 %) of the 145,490 women, we could not determine whether care met the standard, because it was unknown whether they had undergone radiotherapy. The final study cohort consisted of the 144,759 women for whom appropriateness of care could be determined.

Statistical Analysis

The time period from 1983 through 1995 was broken into 3 month periods. The patients were categorized into these periods based on month and year of diagnosis. For each time period, the percentage of women who received appropriate therapy (according to the definition above) was calculated, with the denominator consisting of all cohort patients treated during that time period. Unadjusted percentages are graphed in the figures.

A multivariate logistic model was constructed to permit adjustment of the probability of appropriate therapy for differences in age of patient, stage of disease, ethnicity or size of MSA where the patient resided. Time for each patient was recorded as months after diagnosis. Trends in treatment over time measured in months were modeled using a logistic spline function⁽¹⁴⁾ which allowed knots (linear rate changes in the underlying model for appropriateness with time) at the beginning of the year. In addition, around the time of the NIH consensus conference, knots were allowed semi-annually from 1989 to 1991. A forward stepwise regression analysis was used to include only those knots that were statistically significant. This produced a piecewise linear

logistic fit to the underlying time trend with potential differences for each covariate. Each covariate was fit separately to allow interactions between the covariates and time.

Using the multivariate model, we computed the odds ratio for receipt of appropriate care in 1995 compared to 1988, adjusting for age, race, stage, and size of MSA. Because inappropriate care is not a rare event in this cohort, the odds ratio is a biased estimate of the relative risk. Therefore, we corrected the adjusted odds ratios and confidence intervals to better estimate the adjusted relative risk. ⁽¹⁵⁾

Results

The characteristics of the study cohort are presented in Table 1. About two-thirds of the patients had local stage disease. Most were white and most resided in urban areas. There were increasing numbers of breast cancer patients over time. Overall, about one-third of the patients underwent BCS; the remainder had mastectomy treatment. Consistent with previous reports, ⁽⁶⁻⁹⁾ the use of BCS rose from 1983 to 1985, was relatively stable through mid-1990, then rose steadily through 1995 (Fig.1).

The unadjusted percentage of women in the cohort receiving appropriate primary therapy was about 88% until the late 1980's (Figure 1), then decreased to about 78% at the end of 1995. The multivariate model, which adjusted for age, race, stage, and size of MSA, showed a consistent decrease from the second half of 1990 through 1995. For the cohort overall, the adjusted relative risk of receipt of appropriate therapy in 1995 compared to 1988 was 0.90 (95% confidence interval 0.88, 0.91) .

Figure 2 (top section) shows the unadjusted percentage of women undergoing appropriate therapy, by age group. In the multivariate model, the average percentage

receiving appropriate therapy over the entire time period was lower among women aged 65-79 years than among younger women ($p < 0.001$), and was much lower among women aged 80 and older ($p < 0.001$). We simultaneously examined the rate of decrease in appropriateness over time by age group. The decline from mid-1990 through 1995 was greatest among women aged 64 and younger, with a smaller rate of decline over time among women aged 65-79 years ($p < 0.001$), and the least decline among women aged 80 and older ($p < 0.001$).

Compared to white women, non-white women had a slightly lower average percentage receiving appropriate care in the multivariate model ($p = 0.03$). However there was no racial difference in the rate of decline in appropriateness from mid-1990 through 1995 ($p = 0.91$).

Figure 2 (middle section) shows the unadjusted percentage receiving appropriate care, by stage of disease. In the multivariate model, women with local stage disease had a lower average percentage receiving appropriate therapy than those with regional stage disease ($p < 0.001$). This finding must be interpreted cautiously, since part of the definition of appropriate care included undergoing lymph node dissection, and women undergoing lymph node dissection are more likely to be diagnosed with lymph node metastasis (i.e. regional disease). Nevertheless, there was no difference by stage in the rate of decline in appropriateness during the 1990's ($p = 0.27$).

Figure 2 (bottom section) shows the unadjusted percentage receiving appropriate care, by size of the metropolitan statistical area. Women residing in more urban areas had a lower average percentage receiving appropriate therapy in the multivariate model than those residing in less urban areas ($p < 0.01$). The rate of decline in appropriateness

in the 1990's was also greater among women residing in more urban areas ($p < 0.001$). By the end of 1995, about 76% of women residing in MSA's of 250,000 persons or more received appropriate care, compared to 85% of those residing in less urban areas (Fig. 2).

At each SEER site, the adjusted relative risk of receipt of appropriate therapy in 1995 compared to 1988 was less than one, with 95% confidence limits that excluded one. Therefore, a significant decrease in appropriateness of care had occurred at each site, even after adjusting for age, race, stage, and size of MSA (data not shown).

To better determine whether the consensus recommendations were being applied selectively based on prognosis, we determined the percentage receiving appropriate care based on tumor size (Fig. 3). As tumor size data only became available in 1988, we restricted these analyses to women diagnosed from 1988-1995. Among Stage I patients, those with tumor sizes of 0-10mm were slightly less likely than those with tumor sizes of 11-20mm to meet the criteria for appropriate care (Fig. 3). However, the decline in use of appropriate therapy occurred about equally in women with each tumor size. The percentage undergoing appropriate care fell from 84.2% to 72.8% among women with tumors up to 1 cm in size, and fell from 88.0% to 75.7% among women with tumor sizes of 11-20mm. Additionally, the chance of finding positive lymph nodes among women with small tumors was substantial in this cohort. Among the 18,837 women in this cohort diagnosed from 1988-1995 who had a tumor size up to 10mm and underwent axillary lymph node dissection, 2435 (12.9%) had one or more positive lymph nodes. Among the 31,035 women with a tumor size of 11-20mm who underwent axillary dissection, 8868 (28.6%) had one or more positive nodes.

Components of Care Not Meeting the Consensus Standard

Since the decrease in percentage of women receiving appropriate care coincided temporally with a substantial increase in use of BCS, we hypothesized that the decrease in percentage of patients receiving appropriate therapy might be associated with use of BCS. Figure 4 shows the unadjusted percentage of women in the entire cohort receiving care not meeting the consensus standard, stratified by type of treatment undergone. The percent of patients receiving mastectomy treatment not meeting the standard (total mastectomy without lymph node dissection or subcutaneous mastectomy) remained stable at about 2.7% throughout most of the study period. In contrast, the percentage of the total cohort undergoing BCS treatment not meeting the standard (i.e., no radiotherapy and/or no axillary node dissection) rose from about 10% in 1989 to almost 19% at the end of 1995. Therefore, the decline in appropriateness of care overall appears attributable primarily to BCS treatment not meeting the consensus standard. The women undergoing BCS whose care did not meet the standard were about equally likely to have radiotherapy omitted as they were to have axillary node dissection omitted.

We further hypothesized that the decrease in appropriateness of care was related to a decrease over time in the percentage of BCS patients who underwent radiotherapy or lymph node dissection. However, among the subset of women undergoing BCS, the percentage who underwent radiotherapy and axillary node dissection increased during the mid-1980's, and remained stable at about 65% during the 1990's (Fig. 5). Therefore the decrease in percentage of patients in the entire cohort undergoing appropriate treatment was related to the overall increase in use of BCS, and was not attributable to a decrease in the percentage of the BCS patients who underwent radiotherapy and lymph node

dissection (Fig. 5). Of the women who underwent BCS, approximately equal proportions underwent BCS without radiotherapy, BCS without axillary node dissection, and BCS without either radiotherapy or axillary node dissection by 1995. While the annual number of women treated for breast cancer in this cohort increased 13.6% from 1989 to 1995 (from 10,996 women in 1989 to 12,491 women in 1995), the annual number of women receiving conservative treatment not meeting the consensus guideline nearly doubled over the same time period (from 1158 women in 1989 to 2207 women in 1995).

Discussion

We have shown a decrease in the appropriateness of primary therapy for early stage breast cancer from 1990 to 1995, as judged by the U.S. 1990 NIH Consensus Statement criteria. The decline in appropriateness was similar among different age, stage, and racial groups, but was more marked among those residing in more urban areas. The decrease in appropriateness of care is attributable largely to the increased use of BCS in the population, and is about equally attributable to omission of radiotherapy and omission of axillary node dissection among women undergoing BCS.

Although the decline in appropriateness of care in the study population as a whole is attributable to the increased adoption of BCS, there was no decrease during this time period in the percentage of BCS patients who received appropriate care. In fact, the percentage of the BCS patients who underwent appropriate care increased from 1983 to 1987, and remained stable after that time. Rather, the decline in the percentage of the overall study population receiving appropriate care was due to the shift in care from mastectomy treatment to BCS treatment, coupled with the fact that a substantial

percentage of the BCS patients do not receive care meeting the consensus standard, while the vast majority of mastectomy patients do. Therefore, the shift in care from mastectomy to BCS for primary surgical therapy has ironically led to a decrease in the overall percentage of women receiving care that meets the minimum standard of the 1990 consensus statement.

The fact that the decline in appropriate care was greater among women residing in urban areas is probably explained by the greater propensity of urban residents to undergo BCS.^(4, 10, 16) Women with local stage disease are also more likely to undergo BCS than women with regional stage disease,^(10, 11, 16) accounting for part of the reason that women with local stage disease were less likely than women with regional disease to undergo appropriate care at any given time point. However, part of this difference is likely accounted for by the fact that part of the definition of appropriate care was undergoing axillary node dissection, and women undergoing axillary dissection are more likely to be diagnosed with regional disease.

Some physicians or patients might disagree with the consensus statement recommendations for use of radiotherapy and axillary node dissection in certain patient subgroups (e.g. very low risk patients). However, the consistency of the decrease in appropriateness across different age groups, women with different stages of disease, and women with different tumor sizes, does not support such disagreement as an explanation for our findings. Patients are diverse, and consensus panel recommendations cannot be expected to be applied rigidly to every patient. Therefore, it may not be surprising that 100% of women did not undergo therapy meeting the consensus standard. Nonetheless, it is surprising that the percentage of the population meeting the standard would have

declined in the years immediately following the consensus conference. Since these SEER sites include about 10% of the U.S. population, our results suggest that over 22,000 women each year may be receiving initial care that does not meet the consensus standard.

Women treated with BCS who do not receive radiation therapy have local recurrence rates which approach 35% after 5 years.⁽¹⁷⁻²⁰⁾ While such recurrences did not influence survival in the randomized trials of BCS, the use of BCS without radiotherapy has been associated with higher mortality in two population-based observational studies.⁽²¹⁻²²⁾ In addition, local disease recurrence is often psychologically devastating. Some may argue that patients with small tumors and stage I disease who are treated with BCS do not require radiotherapy. However, we are aware of no authoritative group which has recommended against the use of postoperative radiotherapy in any subgroup of women treated with BCS.⁽²³⁾

Some have also argued that axillary node dissection is not necessary in all patients. Axillary dissection has two purposes. It provides effective local control of the axilla, and it provides information which may guide the use of systemic adjuvant treatment, such as cytotoxic chemotherapy. Some have questioned the need for axillary dissection for persons with small tumors, due to lower risk of metastatic disease.^(24, 25) However, it has been established that clinical examination is a poor predictor of axillary lymph node involvement,^(24, 26) and our findings of a 13% rate of positive lymph nodes in women with ≤ 1 cm tumors and a 29% rate among women with 1-2 cm tumors are similar to findings of others.^(24, 26, 27) It has also been proposed that axillary dissection can be omitted if adjuvant chemotherapy would be given anyway, assuming that axillary radiation would be employed to provide local control of axillary disease.^(24, 25, 28)

However, of the patients in this cohort undergoing BCS without axillary dissection, only 41% underwent any radiotherapy, and presumably not all of these underwent axillary radiotherapy. While findings of randomized trials suggest that axillary dissection does not improve survival,^(29,30) in one study in which the performance of axillary dissection led to greater use of adjuvant chemotherapy, survival was prolonged.⁽³¹⁾

It is also possible that some women who did not undergo axillary node dissection underwent sentinel lymph node biopsy.⁽³²⁾ However, this procedure is not accepted as the standard of care,⁽³³⁾ and during the years of this study, SEER personnel believe that the use of this procedure among SEER patients was quite infrequent (personal communication, April Fritz, SEER Quality Assurance, NCI).

A limitation of this study is that the SEER registries collect data regarding only those therapies begun within the first 4 months after initial treatment. Therefore, some women may have undergone radiotherapy that was not included in the registry data because it was delayed until after chemotherapy. However, our finding that the decline in appropriateness was of similar magnitude among those women least likely to undergo chemotherapy (Stage I disease with tumor size $\leq 10\text{mm}$) speaks against delayed radiotherapy as the major explanation for our findings. The available data suggest that the SEER radiotherapy field is more than 90% accurate^(3,34) and our findings with respect to radiotherapy use are in general agreement with the findings of other investigators using the SEER data.^(10,35) The SEER population is somewhat more urban than the rest of the United States,⁽³⁶⁾ so the percentage of women in this cohort receiving appropriate care may be slightly lower than the percentage in the rest of the U.S. The SEER cohort does offer the advantages of a large and diverse group of patients for study,

a population-based cohort, and recognized high overall quality of data collection procedures.

Our results raise concern about translation of breast-conserving therapy into clinical practice in the 1990's. Ironically, the increased utilization of BCS has been associated with an overall decline in the percentage of women receiving appropriate therapy. These findings highlight the need to carefully study the use and outcomes of new therapies as they are adopted into practice.

Acknowledgement

We thank Susan Goodman for assistance with manuscript preparation.

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Table 1.
Characteristics of the Study Population

| | <u>N</u> | <u>%</u> |
|--------------------------|----------|----------|
| <u>Total Cohort</u> | 144,759 | 100% |
| <u>Age Group (years)</u> | | |
| 30-49 | 34,978 | 24.2 |
| 50-64 | 45,870 | 31.7 |
| 65-79 | 48,855 | 33.7 |
| 80+ | 15,056 | 10.4 |
| <u>Race</u> | | |
| White | 126,363 | 87.3 |
| Black | 10,321 | 7.1 |
| Other | 7332 | 5.1 |
| Unknown | 743 | 0.5 |
| <u>Stage</u> | | |
| Local | 94,167 | 65.0 |
| Regional | 50,592 | 35.0 |
| <u>Year of Diagnosis</u> | | |
| 1983 | 8647 | 6.0 |
| 1984 | 9179 | 6.3 |

(Table 1. continued)

| | | |
|--------------------|--------|------|
| 1985 | 10,037 | 6.9 |
| 1986 | 10,525 | 7.3 |
| 1987 | 11,421 | 7.9 |
| 1988 | 11,370 | 7.8 |
| 1989 | 10,996 | 7.6 |
| 1990 | 11,664 | 8.1 |
| 1991 | 12,034 | 8.3 |
| 1992 | 12,086 | 8.4 |
| 1993 | 11,996 | 8.3 |
| 1994 | 12,313 | 8.5 |
| 1995 | 12,491 | 8.6 |
| <u>SEER site *</u> | | |
| San Francisco | 24,681 | 17.0 |
| CT | 23,657 | 16.3 |
| Detroit | 25,042 | 17.3 |
| HI | 5830 | 4.0 |
| IA | 19,350 | 13.4 |
| NM | 7180 | 5.0 |
| Seattle | 20,832 | 14.4 |
| UT | 7107 | 4.9 |
| Atlanta | 11,080 | 7.7 |
| <u>Size of MSA</u> | | |
| < 250,000 | 30,115 | 20.8 |

(Table 1. continued)

| | | |
|------------------------------|----------|------|
| persons | | |
| ≥ 250, 000 | 114, 599 | 79.2 |
| persons | | |
| <u>Surgical Treatment</u> | | |
| Mastectomy | 97, 481 | 67.3 |
| Breast-Conserving Surgery | 47, 278 | 32.7 |

* SEER refers to the Surveillance, Epidemiology, and End Results program of the National Cancer Institute.

Legend

Figure 1.

Use of breast-conserving surgery and use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, among 144,759 women from the Surveillance, Epidemiology, and End Results (SEER) registry, who were diagnosed with early stage breast cancer between 1983 and 1995.

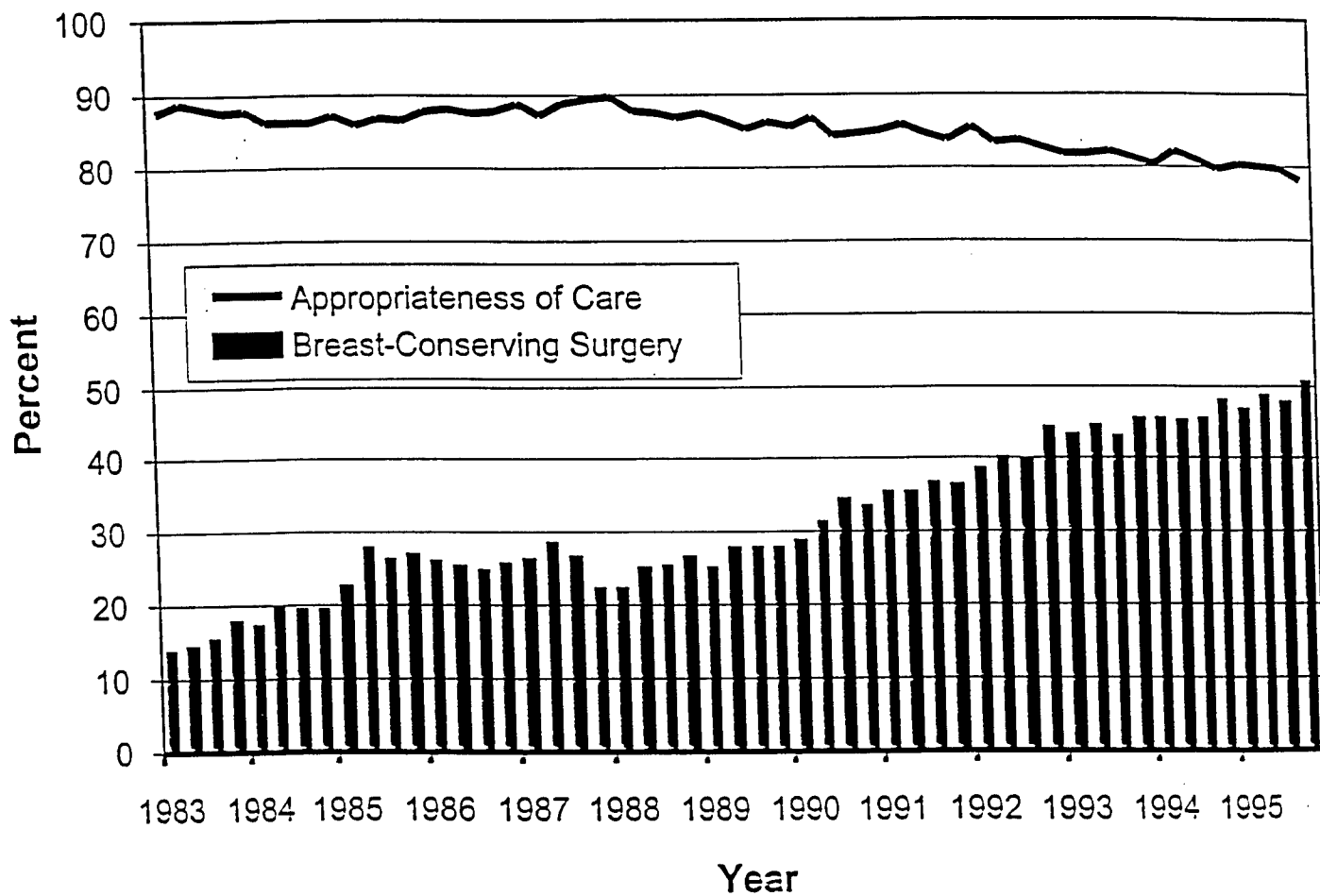


Figure 1.

Legend

Figure 2.

Use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, by patient age at diagnosis (top), by stage at diagnosis (middle), and by size of the metropolitan statistical area (bottom). For the top two graphs, the denominator includes 144,759 subjects from the U.S. SEER registry, who were diagnosed with local or regional breast cancer from 1983 to 1995. For the analyses of size of metropolitan statistical area, 85 women were excluded due to lack of information on county of residence.

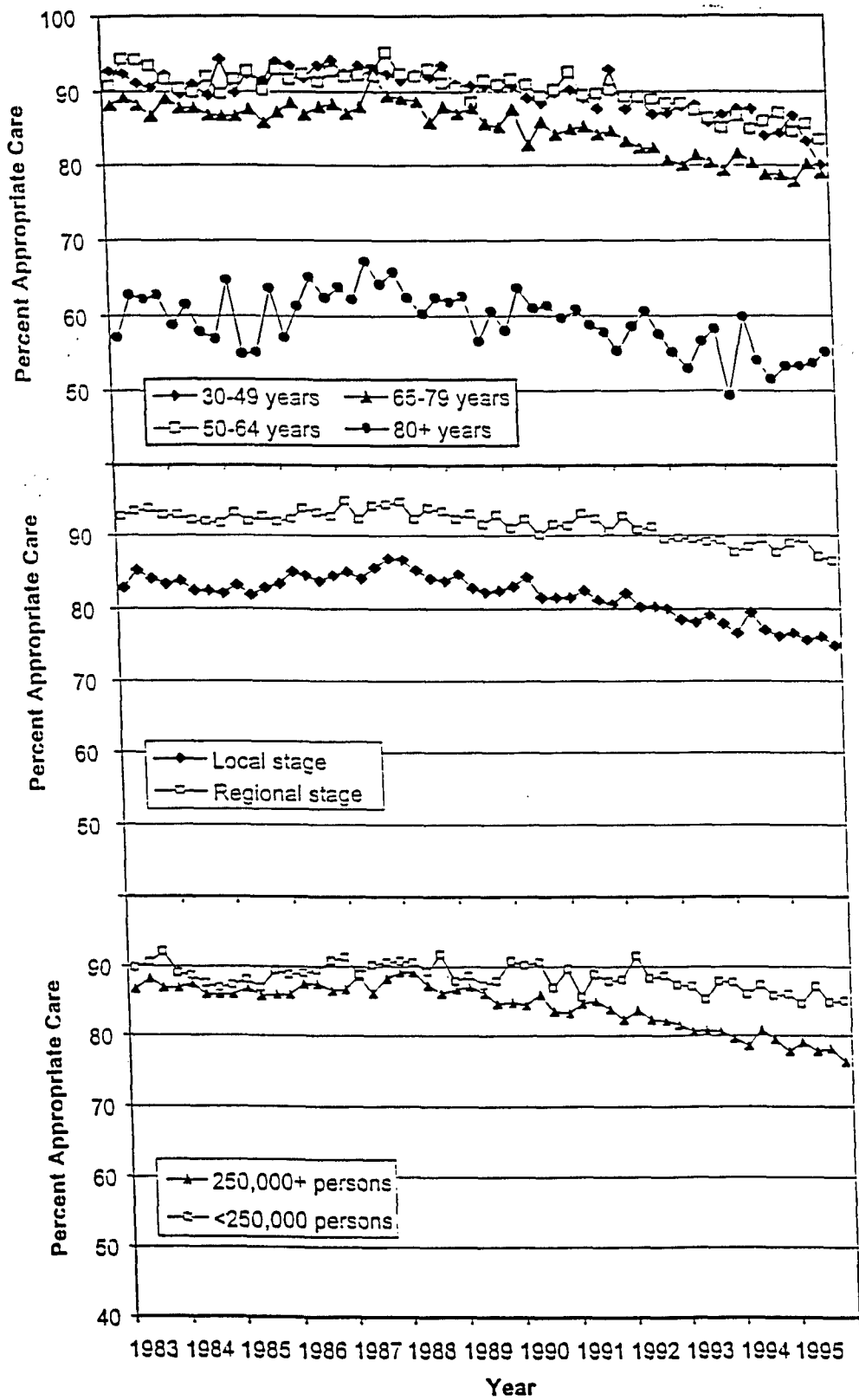


Figure 2.

Legend

Figure 3.

Use of therapy considered appropriate by the 1990 National Cancer Institute Consensus Statement on early stage breast cancer, for stage I patients, by tumor size (0-10mm vs 11-20mm). The denominator includes 45,540 women from the national SEER tumor registry, who were diagnosed with Stage I breast cancer from 1988 to 1995.

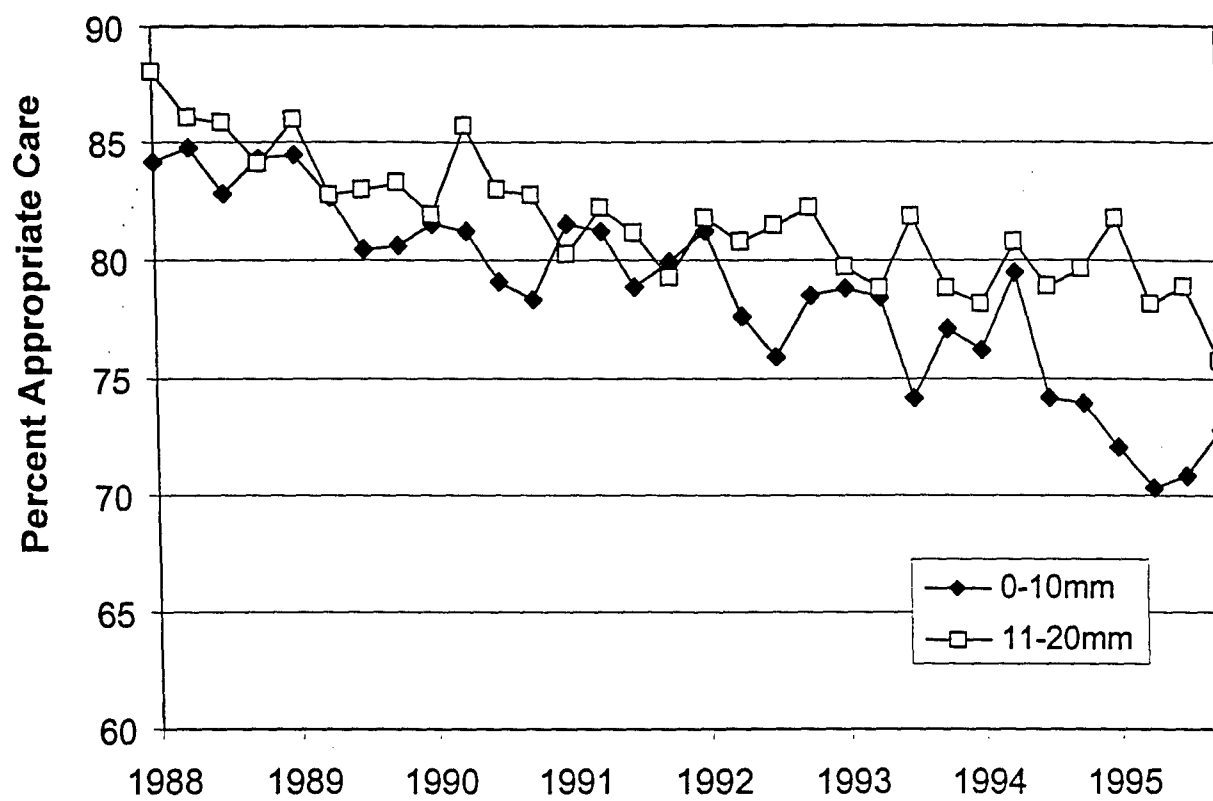


Figure 3.

Legend

Figure 4.

Percentage of women undergoing care that did not meet the 1990 National Cancer Institute Consensus Statement standards, by type of treatment undergone. RT refers to radiotherapy, and LN refers to axillary lymph node dissection. At each time point, the percentage undergoing breast-conserving surgery (BCS) without radiotherapy and the percentage undergoing BCS without axillary lymph node dissection add to more than the total undergoing any inappropriate BCS because some women underwent neither radiotherapy or axillary lymph node excision. The denominator includes 144,759 women diagnosed with local or regional breast cancer from 1983 to 1995, for whom complete treatment information was available.

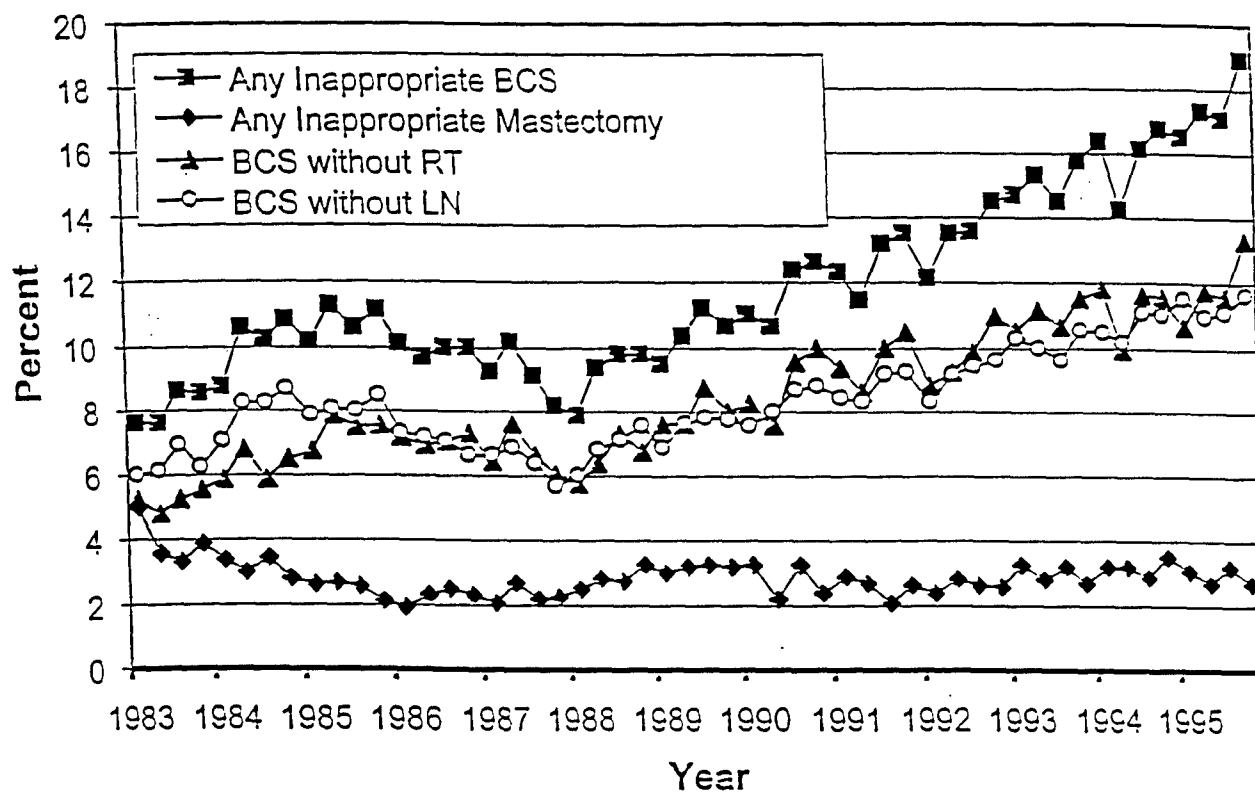


Figure 4.

Legend

Figure 5.

This figure shows the percentage of breast-conserving surgery (BCS) patients who underwent both radiotherapy (RT) and axillary lymph node dissection (LN), or omitted either RT or LN or both. The denominator includes 47,278 women diagnosed with local or regional breast cancer from 1983 to 1995 who underwent BCS for primary therapy.

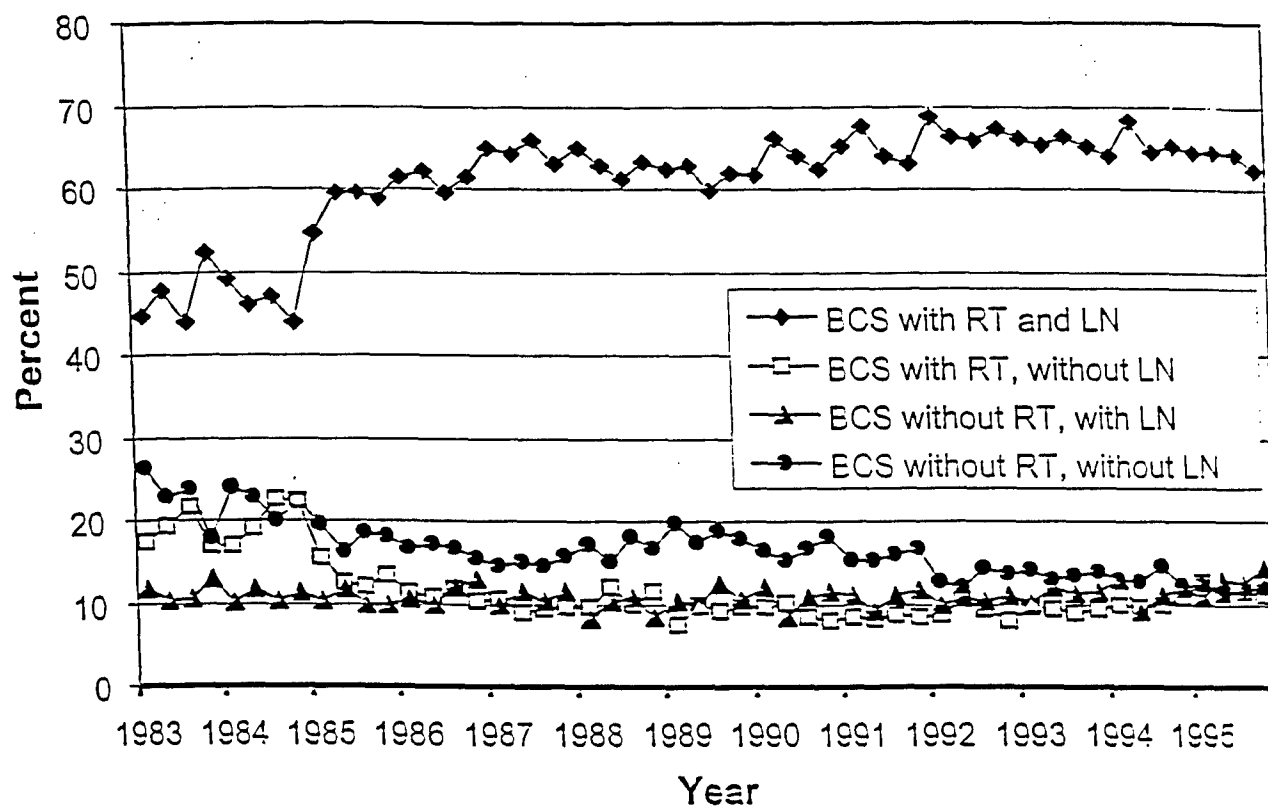


Figure 5.

**The Effect of Axillary Node Dissection on Survival in Women
with Early Stage Breast Cancer**

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Word count: 2,652 words of text, excluding abstract (250 words), acknowledgements, references, 3 tables and 1 figure legend.

Abstract (250 words)

Background: Increasing numbers of older women with early stage breast cancer are receiving breast-conserving surgery (BCS) without axillary dissection. While such an approach appears efficacious in randomized controlled trials, there is concern that it contributes to higher breast cancer mortality in the community.

Methods: We studied 26,290 women with early stage breast cancer aged ≥ 25 in 1983-1993 who received BCS, using data from the Surveillance, Epidemiology and End Results Program and Medicare. Survival analysis was performed using the Cox Proportional Hazard model, controlling for factors known to influence survival.

Results: Twenty seven percent of women aged ≥ 25 receiving BCS did not receive axillary dissection; most of whom (74%) were age ≥ 65 . Women receiving BCS with axillary dissection had lower 7-year breast cancer-specific mortality than did those without axillary dissection (hazard ratio=0.53, 95% confidence interval: 0.44-0.63). We found an interaction between receipt of axillary dissection and radiotherapy on survival of older women after BCS. Women who received either axillary dissection or radiotherapy experienced similar survivals to those who received both axillary dissection and radiation, while women who received neither

treatment experienced poorer survival (hazard ratio=1.76, 1.23-2.52), after controlling for demographics, tumor size and comorbidity.

Conclusions: The combination of no axillary dissection plus no radiation after BCS is associated with an unacceptably high level of deaths from breast cancer. The lack of improvement in the past two decades in survival of older women with breast cancer may be explained in part by the increasing use of treatments that do not address potential tumor in axillary nodes.

Key words: breast cancer, axillary dissection, survival, mortality, breast conserving surgery, SEER, Medicare.

Introduction

Axillary node dissection is a component of modified radical mastectomy, and also is commonly used in breast conserving surgery. There are two major rationales for axillary dissection.¹⁻³ First, it physically removes potentially cancerous tissue in the axilla. Second, it allows for adequate staging information as a guide to more appropriate therapy. It could be argued that these two rationales are less compelling today than in the 1980's and before. For example, radiotherapy to the axillary nodes would accomplish a similar goal to physical removal of cancerous tissue. Also, increased use of adjuvant chemotherapy in early stage breast cancer means that the distinction between local and regional cancer may have less impact on choice of therapy now than it did before.

The necessity or appropriateness of routine axillary dissection is further called into question by the results of randomized controlled trials, which have found no significant differences in 5- or 10-year survival between women receiving breast-conserving surgery with or without axillary dissection.⁴ The reasons outlined above have led some authorities to question the

wisdom of routine axillary dissection,⁵⁻⁸ and this is reflected in an increasing percentage of women with early stage breast cancer who do not receive axillary dissection as part of initial treatment.^{1,9}

On the other hand, there are serious concerns raised by the omission of axillary dissection. It would appear that substantial numbers of older women who do not receive axillary dissection also are not receiving radiation therapy or chemotherapy.^{1,10-12} Approximately 20-50% of women with early stage breast cancer will have positive axillary nodes found on axillary dissection.^{1,13,14} In most women with axillary node metastases there is no indication of metastases on clinical palpation of the axilla.¹³⁻¹⁸ Even women with very small primary tumors of 0.5 to 1.0 cm in size have a greater than 10% incidence of axillary node metastases.^{1,19} It would appear that many of these women are receiving no therapy directed against the axillary node tumor.^{1,10}

While axillary dissection may have little impact on the survival of women otherwise optimally treated and closely followed-up in the context of a randomized controlled trial

(efficacy), there is real concern that the failure to do routine axillary dissection in the community contributes to poorer survival (effectiveness).^{1,9,10,20} For example, in one study of women randomized to undergo or not undergo axillary dissection, women undergoing dissection were more likely to receive adjuvant therapy and also had better survival.²¹ Therefore, we hypothesize that the failure to perform axillary dissection is associated with decreased survival in women diagnosed with early stage breast cancer. To test this hypothesis we examined the survival difference between older breast cancer patients receiving axillary dissection and those without axillary dissection, and examined the role of radiation therapy, chemotherapy and comorbidity. We used a data base in which information from the Surveillance, Epidemiology and End Results (SEER) registry was linked to Medicare Part A and B files.^{22,23} This allows us to better consider factors such as adjuvant radiation therapy and chemotherapy, as well as control for comorbidity, in survival analyses.

Methods

Data Sources

We used two data sources: one is the Surveillance, Epidemiology and End Results (SEER) 1973-96 Public Use Data Set and the other is the merged SEER-Medicare database. The SEER Public Use Data Set was used to examine the seven-year survival rate for cases diagnosed in 1988 and 1989. The SEER-Medicare linked database was used to examine the use of radiation therapy and chemotherapy and to determine comorbidity levels for cases diagnosed between 1991 and 1993. These years were studied because Medicare claims were available for all incident cases diagnosed beginning in 1991.

The SEER program supports population-based tumor registries in four metropolitan areas (San Francisco/Oakland, Detroit, Atlanta, and Seattle) and five states (Connecticut, Iowa, New Mexico, Utah, and Hawaii), covering approximately 10% of the U.S. population.²⁴ Information includes tumor location, size and histologic type; demographic characteristics such as age, gender, race and marital status; and types of treatment provided within four months after the date

early stage (AJCC stage I or stage II) breast cancer at age 65 and older between 1991 and 1993.

After excluding those who received mastectomy, or received no cancer directed surgery, or had missing information on the months of diagnosis, 5,328 who received breast-conserving surgery were included in the analysis.

Treatment and survival

Surgery and axillary dissection. In SEER, breast-conserving surgery (BCS) was defined as segmental mastectomy, lumpectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, excisional biopsy, or partial mastectomy unspecified, with or without dissection of axillary lymph nodes.²⁵

Radiation therapy. We have previously shown that combining data from SEER and Medicare provided the most complete information on radiation therapy.²³ As previously described, receipt of radiation therapy was determined from SEER, supplemented by review of Medicare claims for radiation therapy within 4 months after diagnosis.

Chemotherapy. Chemotherapy was ascertained from the Medicare data through procedure and revenue center codes on at least one claim for chemotherapy made within 12 months after diagnosis of breast cancer. These codes included the ICD-9-CM procedure code 9925 for a hospital inpatient or outpatient facility claim of chemotherapy,²⁷ or the CPT codes of 96400-96549 and J9000-J9999 for a physician or outpatient claim of chemotherapy,²⁸ or revenue center codes 331, 332 and 335 for an outpatient claim of chemotherapy.

Comorbidity index. Comorbidity was ascertained from the Medicare data through ICD-9-CM diagnoses or procedures on claims made 2 years prior to the diagnosis of breast cancer. We used the comorbidity index created by Charlson²⁹ and later validated by Romano and colleagues using the ICD-9-CM diagnosis and procedure codes.³⁰ Comorbidity scores were calculated for each patient. Both the Medicare inpatient and outpatient claims were searched for comorbid conditions, but not including breast cancer diagnosis codes (ICD-9 codes of 174x). Patients who had no inpatient or outpatient Medicare claims during this period were coded as a separate category.

Mortality and Survival Time. Breast cancer-specific death was defined similar to the method of the Early Breast Cancer Trialists' Collaborative Group,⁴ if patients died of breast cancer as a underlying cause of death, or if patients with breast cancer died of unknown causes which was similarly used by other investigator. Information on months of survival from the date of diagnosis was provided in SEER. The last date of the follow-up for this cohort was December 31, 1996.

Analysis

After patients who were lost to follow-up or died of other diseases were censored, a seven-year Kaplan-Meier survival curve was produced using the LIFETEST procedure.³¹ In a separate analysis, all deaths in the first four years were censored and a survival curve from 4 to 7 years was constructed, in order to reduce any effect of comorbidity which might be expected to differentially affect early deaths. The log rank test was used to test the significant differences between stratified curves. In addition, the Cox proportional hazard model was used in the survival analyses using the PHREG procedure available in the SAS statistical package.³¹ These

analyses took into account possible confounding factors such as age, race, marital status, cancer stage, tumor size, SEER area, and comorbidity level.

Results

Table 1 presents the percentages of women receiving breast-conserving surgery (BCS) with or without axillary dissection by patient and tumor characteristics. Overall, 27% of all women with early stage breast cancer who underwent BCS did not receive axillary dissection as part of initial surgical treatment. Older women, unmarried women and those with very small (<0.5 cm) or very large tumors (≥ 4.0 cm) were less likely to receive axillary dissection. The data on the percentages receiving axillary dissection by stage are misleading, because the major means of distinguishing regional from local stage is by axillary dissection. Thus there is a misclassification bias of underreporting regional stage tumor in women without axillary dissection. Because of this, in the survival analyses we control for tumor size rather than stage.

Figure 1 presents Kaplan-Meier survival curves of the 7-year breast cancer specific survival for women receiving BCS with or without axillary dissection. Survival was significantly

greater for women with axillary dissection as compared to those without axillary dissection (P=0.0001). The hazard ratio for mortality at seven years was 0.53 (0.44-0.63) for women with axillary dissection as compared with those without, after adjusting for age, marital status, race, tumor size and SEER area. There was also a significant difference in the survival curves between years 4 and 7 (P=0.0001) after deaths in the first 3 years were censored as a crude control for comorbidity.

As discussed in the Introduction, axillary dissection may be less important if patients not receiving axillary dissection receive adjuvant radiation therapy or chemotherapy. We investigated this issue in women aged 65 and over and diagnosed with early stage breast cancer between 1991 and 1993 using the SEER-Medicare linked data, which provides information on radiation therapy, chemotherapy, and comorbid conditions.²³ Table 2 presents the percentage of women receiving radiation and chemotherapy as a function of receipt of axillary node dissection. Of women receiving BCS without axillary dissection, nearly two-thirds (62%) also did not receive radiation therapy. The great majority of these older women (98%) did not receive

axillary nodes. The percentage of older women who receive no therapy to their axillary nodes has been steadily increasing over the past decade.^{1,32} Third, patients receiving breast-conserving surgery without axillary dissection experience significantly worse survivals than those who do, after controlling for other factors known to affect survival. Finally, there is an interaction between receipt of axillary dissection and radiation therapy on survival, such that women who receive either axillary dissection or radiation therapy experience similar survivals to those who receive both axillary dissection and radiation, while women who receive neither treatment experience substantially poorer survivals.

As noted earlier, in randomized controlled trials of women receiving breast-conserving surgery for early stage breast cancer, axillary dissection has no impact on survival, while the present study and another recent report⁹ found a strong effect of axillary dissection on survival in women treated in the community. We will discuss several possible reasons for this difference.

First, in the randomized trials showing no survival advantage associated with axillary node dissection, all other therapies (e.g., radiation, chemotherapy) were held constant. In actual

without adjuvant radiotherapy did not receive any mammography in the 2 years after initial treatment.

A third potential explanation for the discrepancy between randomized controlled trials and population-based observational studies on the impact of axillary dissection on survival is possible selection bias in the community; that is, women with underlying comorbidity might be less likely to receive axillary dissection and also be at higher risk for death. However, it is important to note that we were assessing only breast cancer-specific mortality, not total mortality. In addition, controlling for underlying comorbidity did not appreciably affect the increased breast cancer-specific mortality associated with axillary dissection. Finally, eliminating all deaths in the first four years after diagnosis, as an additional control for comorbidity, did not eliminate the impact of axillary dissection on breast cancer-specific survival.

We found no difference in survival among those who received axillary dissection plus radiation versus radiation therapy alone. This was unexpected, because those receiving axillary

dissection would be more likely to be correctly staged and therefore more likely to receive chemotherapy and other treatments (Table 2 and reference 21). One reason for this may be that too few women received chemotherapy for there to be a noticeable effect on survival (Table 2).

We should point out the limitations of this study. First, information on chemotherapy from Medicare has not been well validated, and its completeness is unknown. However, information on radiation therapy from the combined sources of SEER and Medicare would appear to be complete.²² Second, there was no information on the use of sentinel node biopsy in SEER, although this procedure may have potential to be a replacement for routine axillary dissection. However, it has still not been confirmed for routine use,³⁴ and it was unlikely to have been widely used during the study period. Finally, information on estrogen-blocking therapy for breast cancer cannot be addressed. We assumed that women not receiving axillary node dissection, who would thus be likely for understaging, would have been less likely to receive estrogen antagonists, just as they were less likely to receive radiation and chemotherapy.

In conclusion, a substantial number of older women with early stage breast cancer in the United States receive BCS without axillary dissection, and most of those women also do not receive adjuvant radiation. This combination of no axillary dissection plus no radiation after BCS is associated with an unacceptably high level of deaths from breast cancer. Breast cancer survival has improved steadily over the past 25 years, except for older women.^{35,36} The lack of improvement in the past two decades in survival of older women may be explained in part by the increasing numbers of older women who receive treatments that do not address potential tumor in the axillary nodes.^{1,9}

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3. Recht A, Houlihan MJ. Axillary lymph nodes and breast cancer: a review. *Cancer* 1995;76:1491-512.
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9. Bland KI, Scott-Conner CE, Menck H, Winchester DP. Axillary dissection in breast-

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Table 1. Receipt of axillary dissection by women with breast cancer who received breast conserving surgery (BCS) between 1988 and 1993 in 9 SEER areas, by patient and tumor characteristics

| Patient and tumor characteristics | Number (%) of women receiving BCS* without axillary dissection | Number (%) of women receiving BCS* with axillary dissection | Total |
|--|---|--|--------------|
| Age (years) | | | |
| 25-54 | 931 (10.2) | 8173 (89.8) | 9104 |
| 55-64 | 835 (15.2) | 4674 (84.8) | 5509 |
| 65-74 | 1604 (26.0) | 4573 (74.0) | 6177 |
| 75+ | 3421 (62.2) | 2079 (37.8) | 5500 |
| Race | | | |
| White | 6021 (26.0) | 17145 (74.0) | 23166 |
| Black | 463 (26.1) | 1313 (73.9) | 1776 |
| Other | 252 (20.9) | 955 (79.1) | 1207 |
| Unknown | 55 (39.0) | 86 (61.0) | 141 |
| Marital status | | | |
| Married | 2588 (17.4) | 12276 (82.6) | 14864 |
| Unmarried | 3866 (36.0) | 6876 (64.0) | 10742 |
| Unknown | 337 (49.3) | 347 (50.7) | 684 |
| Cancer stage | | | |
| Stage I | 5143 (28.7) | 12750 (71.3) | 17893 |
| Stage IIA | 1442 (22.4) | 4998 (77.6) | 6440 |
| Stage IIB | 190 (10.8) | 1564 (89.2) | 1754 |
| Stage II,NOS † | 16 (7.9) | 187 (92.1) | 203 |

Table 1 (continued)

| Tumor size (cm) | | | |
|------------------------|--------------------|---------------------|--------------|
| <0.5 | 472 (38.9) | 743 (61.1) | 1225 |
| 0.5-<1.0 | 1294 (25.0) | 3883 (75.0) | 5177 |
| 1.0-<2.0 | 2857 (23.9) | 9089 (76.1) | 11946 |
| 2.0-<3.0 | 1362 (25.2) | 4053 (74.8) | 5415 |
| 3.0-<4.0 | 466 (30.4) | 1066 (69.6) | 1532 |
| 4.0+ | 324 (40.4) | 478 (59.6) | 802 |
| Unknown size | 16 (7.9) | 187 (92.1) | 203 |
| Total | 6791 (25.8) | 19499 (74.2) | 26290 |

* BCS denotes breast-conserving surgery.

† NOS - not specified.

Table 2. Receipt of radiation therapy and chemotherapy in women aged 65 and older who underwent breast conserving surgery in 1991 through 1993, with or without axillary node dissection*

| Surgical treatment categories | Number of patients | Number (%) of women receiving radiation therapy † | Number (%) of women receiving chemotherapy ‡ |
|--|-------------------------------|--|---|
| breast conserving surgery | | | |
| without axillary dissection | 2215 | 853 (38.5) | 52 (2.4) |
| breast conserving surgery | | | |
| with axillary dissection | 2974 | 2673 (85.9) | 163 (5.2) |

* For women with early stage (local or regional) breast cancer diagnosed between 1991 and 1993 from the SEER-Medicare linked database.

† Radiation therapy was defined if SEER data indicated so or if there were Medicare claims for radiation therapy within 4 months after diagnosis of breast cancer.

‡ Chemotherapy was defined if patients had at least one Medicare claim for chemotherapy within 12 months after diagnosis.

Table 3. Interaction between receipt of axillary dissection and radiation therapy on breast cancer survival in women aged 65 and older with early stage breast cancer, 1991-1993

| Variables | Number of patients (n=5328) | Hazard ratio for 3-year breast cancer specific mortality (95% CI) † |
|--|-----------------------------------|---|
| Patients receiving BCS, by receipt of axillary dissection (Ax) and radiation (XRT)* | | |
| No Ax + no XRT | 1362 | 1.76 (1.24-2.49) |
| No Ax + XRT | 853 | 1.11 (0.74-1.68) |
| Ax + no XRT | 440 | 1.00 (0.59-1.70) |
| Ax + XRT | 2673 | 1.00 |
| Other key risk factors in the model | | |
| Age (years) | | |
| 65-69 | 1287 | 1.00 |
| 70-74 | 1415 | 1.03 (0.69-1.53) |
| 75-79 | 1189 | 1.02 (0.67-1.54) |
| 80+ | 1437 | 1.15 (0.76-1.74) |
| Tumor size (cm) | | |
| <0.5 | 264 | 1.00 |
| 0.5-<1.0 | 1252 | 1.11 (0.42-2.93) |
| 1.0-<2.0 | 2419 | 2.07 (0.84-5.12) |
| 2.0-<3.0 | 968 | 3.51 (1.40-8.77) |
| 3.0-<4.0 | 255 | 6.76 (2.62-17.44) |
| 4.0+ | 138 | 5.50 (2.00-15.12) |

Table 3 (continued)

| | | |
|-----------------------------------|------|------------------|
| Unknown size | 32 | 2.52 (0.89-7.09) |
| Comorbidity index scores ‡ | | |
| No Medicare claims | 344 | 0.82 (0.44-1.54) |
| 0 | 3616 | 1.00 |
| 1 | 637 | 1.53 (1.06-2.22) |
| 2 | 323 | 1.76 (1.11-2.79) |
| 3+ | 408 | 2.05 (1.37-3.05) |

* BCS (breast-conserving surgery), No Ax (no axillary dissection); no XRT (no radiation therapy); Ax (axillary dissection); XRT (radiation therapy).

† Hazard ratios (95% confidence interval), adjusted for the variables listed in the table and also adjusted for marital status (married, unmarried and unknown), race (white, black, and other), and 9 SEER areas.

‡ Comorbidity was assessed by a validated algorithm^{29,30} using Medicare claims.

Legend for Figure 1.

Figure 1. Kaplan-Meier breast cancer specific survival curve for women with early stage breast cancer, stratified by breast conserving surgery (BCS) with and without axillary dissection.

The 7-year breast cancer specific survival curves are shown. The log rank test for survival curves between BCS without axillary dissection and BCS with axillary dissection was statistically significant for two groups ($P=0.0001$). Data are for all women aged 25 and older diagnosed with early stage breast cancer in one of the 9 SEER areas in 1988 and 1989 ($n=27,638$), and followed through 1996.

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EDUCATION

1979 B.S., University of Illinois at Urbana-Champaign
1983 M.D., University of Illinois College of Medicine, Chicago
1988 M.P.H. University of Rochester School of Med & Dentistry

POSTGRADUATE TRAINING AND FELLOWSHIP APPOINTMENTS

1983-1986 Resident in Medicine,
Primary Care Program in Internal Medicine
Strong Memorial Hospital, University of Rochester
1986-1988 Fellow, General Medicine Unit, Strong Memorial
Hospital, University of Rochester

FACULTY APPOINTMENTS

1983-1986 Assistant in Internal Medicine
School of Medicine and Dentistry,
Strong Memorial Hospital, University of Rochester
1986-1987 Instructor and Fellow in Internal Medicine,
School of Medicine and Dentistry, Strong
Memorial Hospital, University of Rochester

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|---------|--|
| 1988-95 | Assistant Professor of Medicine, Medical College of Wisconsin |
| 1989- | Director of Health Services Research, Div. of General Internal Medicine, Medical College of Wisconsin |
| 1993-95 | Assistant Professor of Health Services Research, Health Policy Institute, Medical College of Wisconsin |
| 1995- | Associate Professor of Medicine and Health Services Research, General Internal Medicine, Medical College of WI |
| 1997-98 | Associate Chief of General Internal Medicine |
| 1999- | Chief of General Internal Medicine |

SPECIALTY CERTIFICATION

| | |
|------|-------------------------------------|
| 1984 | National Board of Medical Examiners |
| 1986 | American Board of Internal Medicine |

LICENSURE

New York and Wisconsin (WI#29279)

HONORS, AWARDS

| | |
|------|--|
| 1979 | Summer Fellowship, The Chicago Heart Association |
| 1980 | Summer Fellowship, The Research Scholars Program University of Illinois, School of Basic Medical Sciences |
| 1986 | Lawrence E. Young Book Award, University of Rochester (Best Third Year Resident) |
| 1990 | Excellence in Attending Award, Dept. of Med., MCW |
| 1994 | Central Society for Clinical Research |
| 1996 | Division of GIM awarded "Best Teaching Service", by Medicine Housestaff |
| 1997 | Division of GIM awarded "Best Teaching Service", by Medicine Housestaff |
| 1998 | Fellow, American College of Physicians |
| 1999 | Division of GIM awarded "Best Teaching Service", by Medicine Housestaff |
| 1999 | Recipient of "The Learning Resources Innovative Educational Project Award", MCW |

MEMBERSHIPS IN PROFESSIONAL AND HONORARY SOCIETIES

| | |
|--------------|--------------------------------------|
| 1986-present | American College of Physicians |
| 1986-present | Society of General Internal Medicine |

Offices held

| | |
|---------|--------------------------------------|
| 1990-92 | Coordinator, National Women's Caucus |
| 1991-92 | Counsellor, Midwest Region |
| 1992-93 | Chairperson-Elect, Midwest Region |

1993-94 Chairperson, Midwest Region
1993-94 Co-Chair, Annual National Meeting
1994-97 National Council Member

Committees

1989 Workshop Selection Committee, National Meeting
1989 Abstract Selection Committee, Regional Meeting
1990 Fellow's Award Committee, Midwest Region
1992 Trainee Award Committee, National Meeting
1992 Trainee Award Committee, Midwest Meeting
1994 Continuing Medical Education Committee
1995 Abstract Selection Committee, National Meeting
1995-97 Education Committee
1995-97 Membership Committee
1996 Chair, Clin Epi Abstract Committee, National Mtg
1996-Development Task Force
1997 HSR abstract Committee, National Mtg
1998 HSR abstract Committee, National Mtg
2000 Glaser Award Selection Committee
1987 American Public Health Association
1988 Society for Medical Decision Making
1992 American Geriatrics Society
1994 Central Society for Clinical Research (invited)
1995-98 Council Member
1995 Association for Health Services Research
1999 Milwaukee Academy of Medicine

EDITORIAL BOARDS

1996-99 Editorial Board, Journal of General Internal Medicine
1996- Editorial Board, American Journal of Medical Sciences

Manuscript Reviewer for the Journal of General Internal Medicine,
American Journal of Medicine, Annals of Internal Medicine, Journal of the
National Cancer Institute, Medical Care, Cancer, American Journal of Public Health, Institute of
Medicine

NATIONAL ADVISORY COMMITTEES AND/OR ACTIVITIES

1990-92 Coordinator, National Society of General Internal Medicine Women's Caucus
1993 Agency for Health Care Policy and Research. Invited participant for the
program "Medical Effectiveness Research: Strategies for the Future", a
discussion of the future of the PORT program. February 17-18, 1993
1993-94 Co-Chair, Society of General Internal Medicine National Annual Meeting
Co-Responsible for entire scientific program, including abstracts, workshops,
precourses, mentoring program.
1993-00 American Cancer Society, national office. Member, Medical Affairs
Advisory Group on Primary Care Physicians Awards. (Study section to

- select recipients of ACS Primary Care Physicians Career Development Awards).
- 1998-00 Chair
- 1994-97 Elected to National Council of the Society of General Internal Medicine. Two persons per year nationally are elected as councilors.
- 1997 American Cancer Society – national office. Member, Peer Review Group to conduct site visit of ACS Intramural Epidemiology & Surveillance Programs. Committee Chair: Jonathon Samet, MD.
- 1998 Ad Hoc Reviewer, Agency for Health Care Policy and Research small grants program.

COMMUNITY ADVISORY COMMITTEES AND/OR ACTIVITIES

- 1989-93 American Cancer Society, Wisconsin Physician Education Subcommittee
- 1990-95 American Cancer Society, Wisconsin Cancer Prevention and Early Detection
 - 1994 Co-Chair
- 1995-98 American Cancer Society, Wisconsin
 - Detection Policy Task Force Committee.
- 1995- American Cancer Society, Wisconsin
 - Research and Clinical Issues Committee

MEDICAL COLLEGE COMMITTEES

- 1988- Member, Cancer Center
- 1993-97 Women's Faculty Council
 - 1994-96 Chair, Program Planning Committee
 - 1995-96 Chair-elect
 - 1996-97 Chair
- 1993-97 Faculty Welfare Committee
- 1994 Search Committee for Chair of Preventive Medicine
- 1994 Chair, Outcomes Measurement Work Group
- 1995 Clinical Task Force for Strategic Planning
- 1997-98 Board Member, Clinical Practice Group
- 1998-99 Chair, Medical Effectiveness Task Force
- 2000 General Clinical Research Center Advisory Board

DEPT. OF MEDICINE COMMITTEES

- 1992-98 Advisory Committee on Rank & Tenure
- 1992- Residency Curriculum Committee
- 1992-93 Advisory Committee on Search for GIM Div. Chief
- 1996-97 Research Committee
- 1998- Faculty Development Committee

DIVISION OF GIM COMMITTEES

- 1988-93 General Medical Clinic Team Leader
- 1989-93 Research Committee, Co-director
- 1989-93 Executive Committee
- 1993-98 Chair, Research Strategic Planning Committee

1994-97 Chair, Inpatient Education Subcommittee
1995- Management Team
1998- Research Committee

HOSPITAL COMMITTEES

1998- Clinical Management Committee, FMLH
1999- Hospital Advisory Committee, FMLH

INVITED PRESENTATIONS, WORKSHOPS

"Lifestyle Issues Impacting the Faculty Development of Academic Internists." Coordinator and moderator of panel discussion at the Society of General Internal Medicine National meeting, Washington, D.C., April 29, 1988.

"Prevention of Postmenopausal Osteoporosis: Are Two Hormones Better Than One?" Moderator of debate at Society of General Internal Medicine National meeting, Washington, D.C., May 1990.

"Faculty Development and Mentorship in General Internal Medicine." Panel Discussion at SGIM Midwest Regional meeting, Chicago, IL, Nov. 1990.

"Screening for Breast Cancer", presented at the Wisconsin State ACP meeting, Madison, WI, Sept. 1990.

"Breast Cancer Screening in the Elderly Woman", Lecture at the Annual Fall Conference on Geriatrics, Midwest Geriatric Education Center, Milwaukee, WI, Sept. 7, 1990.

"Mentoring in Academic General Internal Medicine: Finding and Becoming a good Academic Parent." Panel Discussion at SGIM National Meeting, Seattle, WA, May, 1991.

"Breast Cancer in the Older Woman: Barriers to Care", Medical Grand Rounds and Visiting Professor, Henry Ford Hospital, Detroit, MI, Dec, 1991.

"Working Part-time in the Academic Setting: A Viable Option?" Panel discussion at SGIM National Meeting, Washington, DC, May, 1992.

"Variation in Breast Cancer Treatment", Plenary presentation at Central Society for Clinical Research, Chicago, IL, Nov. 6, 1992.

"Women in Academic Medicine", invited presentation to Regional AMWA Student-Doctor Annual Meeting, Milwaukee, WI, Feb. 1993.

"Community Variation in Breast Cancer Treatment", Plenary presentation at University of Wisconsin Meeting: Providing Health Care to the Local Community: What Do We Need and How Do We Know It? Milwaukee, WI April 3, 1993.

"Promotion of Women in Academic Medicine", Plenary presentation, A Clinical Symposium Honoring Rudolph J. Napodano, M.D., Rochester Academy of Medicine, Rochester, NY, April 24, 1993.

"Linkage of AHA and Medpar Databases", Plenary presentation, "Linkage of Central Cancer Registries with Secondary Databases." Sponsored by National Cancer Institute and Medical College of Virginia, Richmond, VA, November 12, 1993.

"Variations in Breast Cancer Treatment", invited presentation to Regional AMWA Student-Doctor Annual Meeting, Milwaukee, WI, March 19, 1994.

"Cancer Screening in Primary Care Practice" and "Variation in the Use of Breast Conserving Surgery", 18th Annual Solomon Papper Humane Scholarship Lectures, University of Oklahoma Health Services Center, Oklahoma City, OK, March 23, 1994.

"Variations in Breast Cancer Treatment", Medical Grand Rounds, St. Luke's Hospital, Milwaukee, WI, June 9, 1994.

"Issues of Detection and Etiology", Northern Illinois Medical Center-Symposium" Cancer Challenges 1994-Breast & Prostate", McHenry, Illinois, June, 1994.

"Breast Cancer Screening and the Clinical Breast Exam", workshop presentation at SGIM National Meeting, San Diego, CA, May, 1995.

"Exploring Career and Family Dilemmas", workshop presentation at SGIM National Meeting, San Diego, CA, May, 1995.

"Breast Cancer Screening in the Older Woman", plenary presentation "Cancer in Older People", at Lake Geneva, WI, June 9, 1995.

"Breast Cancer Screening: Standards and Strategies", invited lecture at The University of Michigan Medical School, Ann Arbor, MI, April 29, 1996.

"Colorectal Cancer Screening: The Latest Poop", workshop presentation at the Midwest SGIM meeting, Chicago, IL, Sept 27, 1997.

"Update on Women's Health-1997". Invited speaker at The American College of Physicians National meeting. San Diego, CA. April 2-5, 1998.

"Career Development Awards: How To Get One", workshop presentation at the Society of General Internal Medicine National Meeting. April 23-25, 1998, Chicago, IL.

"Colorectal Cancer Screening: Clinical Update and Controversies", workshop presentation at the National Society of General Internal Medicine meetings in Chicago IL, April 23-25, 1998.

"Breast and Cervical Cancer: Where Are We Going? How Might We Get There", plenary talk at a conference Sponsored by Wisconsin Cancer Council, June 25, 1998, Oconomowoc, WI.

"How Do We Treat Women with Breast Cancer? Studies in Variation in Care", lecture at University of Chicago, Chicago, IL, July 15, 1998.

"Breast Cancer in Older Women", lecture at Wisconsin Board Review Course in Geriatric Medicine. Delavan, WI, September 23-26, 1998.

"How Do We Treat Women with Breast Cancer? Observations from Studies of Variation in Care", lecture at University of California at San Francisco, San Francisco, CA, October 26, 1998.

"Update in Women's Health – 1998". Invited speaker at the American College of Physicians national meeting. New Orleans, LA, April 22, 23, 1999.

"Breast Cancer Screening", Plenary speaker at the New York Downstate Scientific meeting of the New York ACP-ASIM Chapter. New York, NY, May 15, 1999.

"Promotion of Women in Academic Medicine," invited presentation at the Regional American Medical Women's Association meeting. Milwaukee, WI, August 21, 1999.

"Rekindling Career Passion in Mid-Life", workshop presentation at the Society of General Internal Medicine Midwest Regional Meeting. September 16-18, 1999, Chicago, IL.

RESEARCH GRANTS, CONTRACT, AWARDS

Innovation in Patient Care Program, Strong Memorial Hospital. Co-principal Investigator. Total Direct Costs: \$10,200 1987-1988. "Holter Monitoring in the Patient with Focal Neurologic Deficit."

American Cancer Society Institutional Grant. Principal Investigator of Seed Grant. Total Direct Costs: \$7,200 Jan. 1, 1989-Dec. 31, 1989. "Relation of Age and Ethnicity to Patterns of Treatment for Breast Cancer".

Public Health Service Grant, National Cancer Institute R01-CA54676. Principal Investigator at 40% effort. Total Direct Costs: \$49,099, April 1, 1991-June 1992. "Use of Breast-Conserving Surgery in the Elderly."

Public Health Service Grant, National Cancer Institute R01-CA54676. Principal Investigator at 35% effort. Total Direct Costs: \$286,271, May 24, 1993-April 30, 1997. "Use of Breast-Conserving Surgery in the Elderly."

VA HSR&D #92-609. Co-Investigator at 10% effort. Total Direct Costs: \$508,000, July 1, 1993-June 30, 1996. "Clinical Decision Making and Prostate Cancer." PI: Marilyn Schapira, M.D.

Department of Defense, DAMD17-94-J4043. Principal Investigator at 25% effort. Total Direct Costs \$525,667. September 1994-August 1999. "Surveillance After Initial Treatment for Breast Cancer: A Population-Based Study of Variation and Outcomes of Care".

Department of Defense DAMD17-96-6262. Principal Investigator at 25% effort. Total Direct Costs: \$540,000, Sept 1996-Aug 2000. "Early Stage Breast Cancer in Older Women: Predictors and Outcomes of Therapy".

National American Cancer Society, Cancer Control Career Development Award for Primary Care Physicians. Mentor at 5% effort (donated) for award to Marilyn M. Schapira, M.D. Total Direct Costs: \$140,000. July 1, 1997-June 30, 2000.

National American Cancer Society, Cancer Control Career Development Award for Primary Care Physicians. Mentor at 5% effort (donated) for award to Mary Ann Gilligan, M.D. Total Direct Costs: \$165,000. July 1, 1999-June 30, 2002.

HRSA, National Research Service Award T3Z-PE10030. Co-Program Director at 10% effort. PI: Linda Meurer, MD. Total direct costs \$1,308,420, July 1, 1998-June 30, 2003. "Academic Fellowship in Primary Care Research."

PHS, National Cancer Institute 1U01CA/E581773. Site Principal Investigator at 15% effort. PI: James S. Goodwin, MD. Total Direct Costs for site: \$283,969, June 1, 1999 – March 31, 2003. "Regional Variation in Breast Cancer Rates in the U.S."

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21 Feb 03

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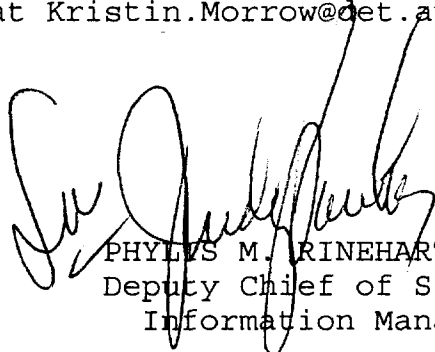
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